European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

The Future of Cancer Care: Advancing Innovation, Research, and Digitalisation in medical technology under new EU Legislative Frameworks

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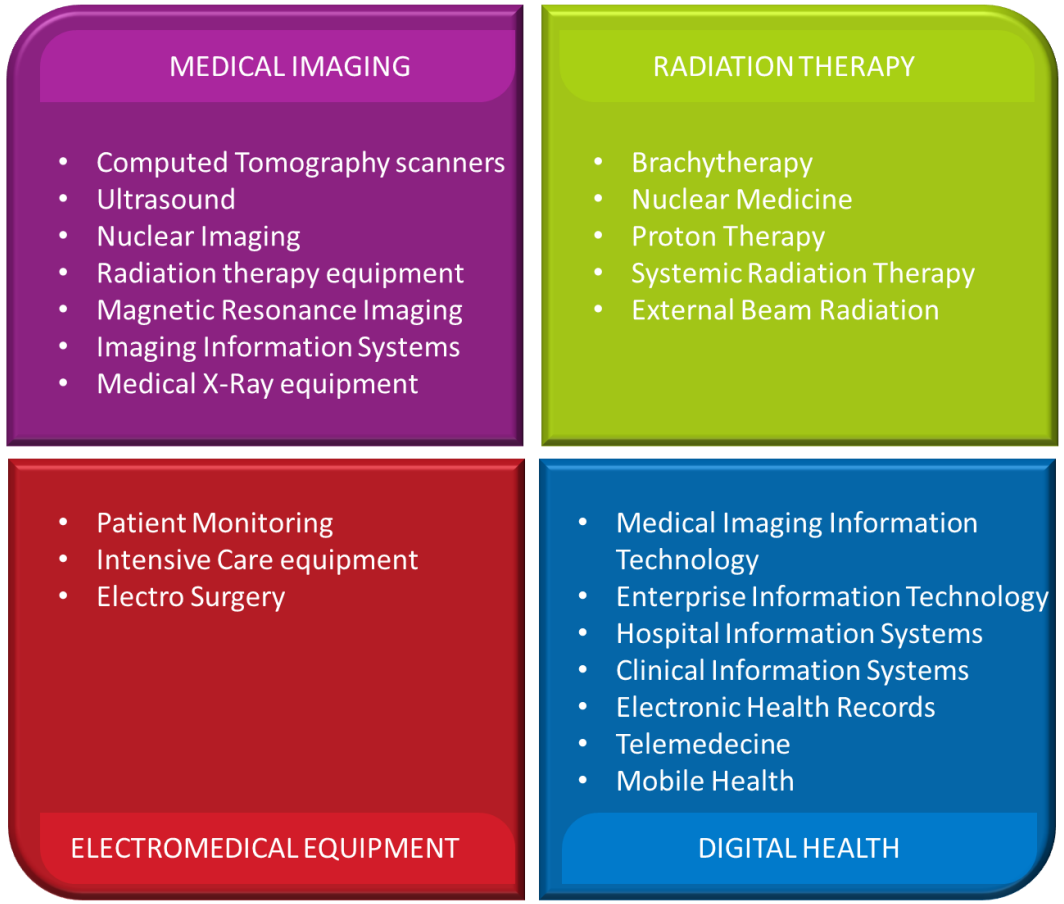
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry



- COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe.
- Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle
- COCIR covers 4 key industry sectors
  - Medical Imaging
  - Radiotherapy
  - Health ICT
  - Electromedical

Impact of EU Legislative Frameworks on Innovation

a. MDR/IVDR Regulations

The EU's Medical Device Regulation (MDR) impose stricter requirements on device certification, clinical evidence, and post-market surveillance. This is critical for radiotherapy devices, which often involve high-risk classifications.

- **Challenge**: Increased time and cost to bring new devices or updates to market.
- **Opportunity**: Enhanced safety and efficacy standards can foster trust in innovative solutions.

b. Harmonized Standards and Guidelines

The EU's initiatives to harmonize standards encourage consistency in device safety and performance.

- **For Manufacturers**: Compliance requires more robust evidence, incentivizing early collaboration with regulators and thorough R&D.

c. Digital Health and AI Regulation

The proposed European Health Data Space (EHDS) and AI Act aim to govern the use of data and artificial intelligence in healthcare.

- **Challenge**: Navigating compliance for AI-powered radiotherapy planning tools and treatment algorithms.
- **Opportunity**: Access to shared health data can enhance personalized treatments and predictive analytics

Advancing Innovation

a. Adaptive and Precision Radiotherapy

Radiotherapy manufacturers are focusing on:

- **Real-time imaging**: Enhances tumor targeting while sparing healthy tissues.
- **Adaptive therapy**: Devices that adjust to changes in tumor size/shape during treatment.
- **Impact of Legislation**: Stricter validation processes for adaptive radiotherapy systems may delay rollout but improve quality.

b. Proton and Carbon Ion Therapy

Next-generation treatments are gaining traction, offering superior precision.

- **Regulatory Hurdle**: Compliance with MDR for complex particle therapy systems requires significant clinical evidence.

c. Software as a Medical Device (SaMD)

AI-driven software is essential in dose optimization and workflow management.

- **Regulatory Implication**: Alignment with the EU's digital standards and cybersecurity frameworks is paramount

Digitalisation in Health Technology

a. Digital Twin Technology

Digital twins for personalized radiotherapy planning are revolutionizing patient care. They require:

- **Interoperability Standards**: Compliance with EU digital health regulations to ensure seamless data exchange.

b. Cloud-Based Treatment Platforms

Digital platforms for remote monitoring and treatment planning are crucial, especially post-pandemic.

- **Regulatory Consideration**: GDPR compliance for patient data security and privacy.

Challenges and Recommendations

Challenges

- **Regulatory Compliance**: Adapting to MDR/IVDR and digital health laws.
- **Cost Pressure**: Balancing innovation with increased compliance costs.
- **Market Access**: Ensuring devices meet EU standards without significant delays.

Recommendations

1. **Early Engagement**: Collaborate with notified bodies and regulators early in the design phase.
2. **Invest in R&D**: Develop modular and scalable technologies to adapt to future regulations.
3. **Digital Integration**: Build AI and digital capabilities while ensuring data privacy compliance.
4. **Continuous Training**: Equip teams with knowledge on new legislative frameworks.

innovative health initiative

WHAT IS IHI?

FROM IMI TO IHI

IHI PARTNERS

IHI IS EUROPE'S NEW PARTNERSHIP FOR HEALTH

IHI is a **collaboration** between the EU and the biopharmaceutical, biotechnology, digital health and medical technology sectors, as well as academics, patients, regulators and other healthcare professionals.

IHI will build on the extensive experience of **IMI's 14 years and almost 200 projects** to build an interdisciplinary, sustainable, patient-centric health research partnership to help transform patients' lives.

The industry members that make up the new partnership are:

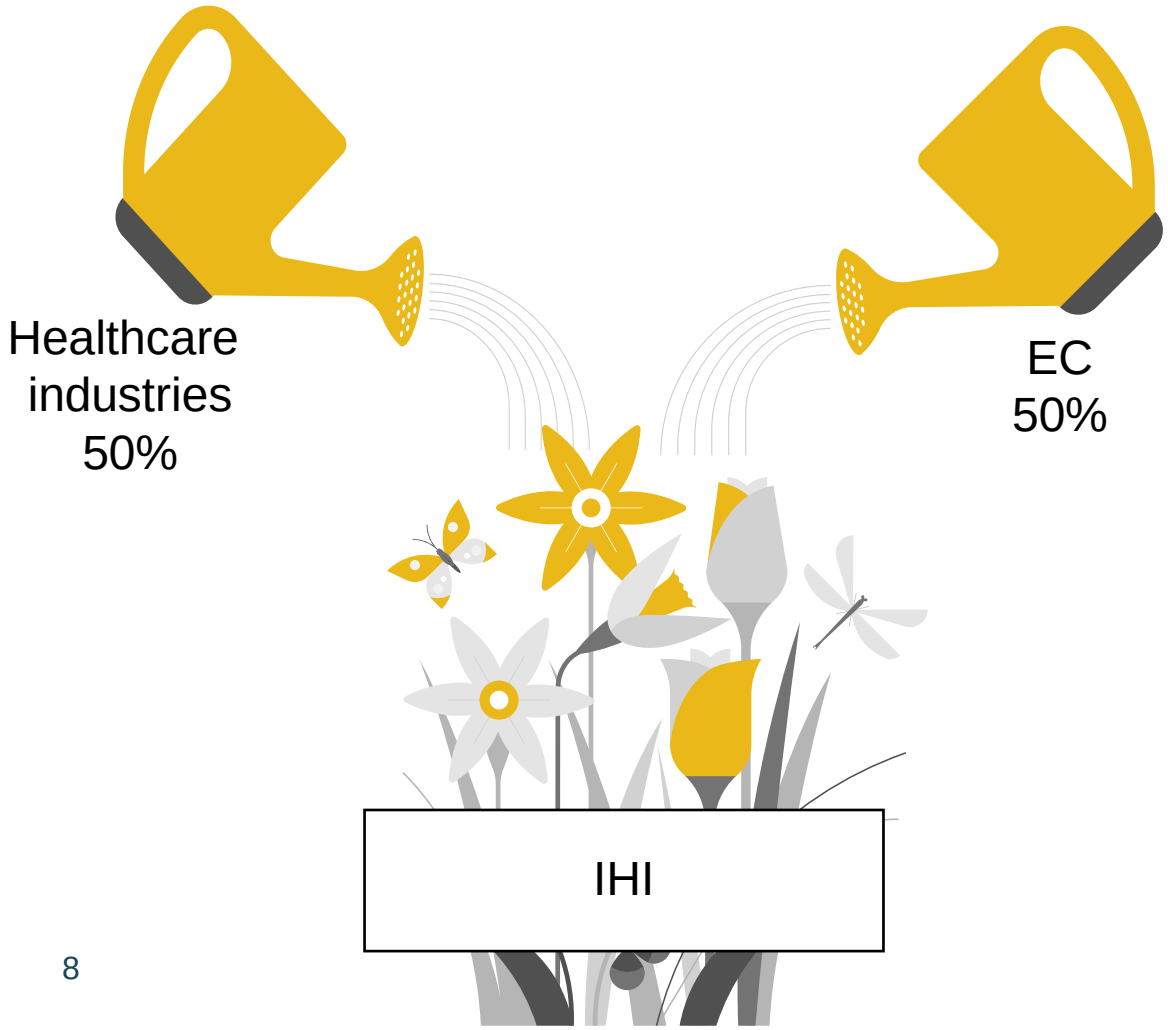
- COCIR
- EFPIA
- EuropaBio
- MedTech Europe
- Vaccines Europe

The public member in the partnership is the European Union, represented by the European Commission

www.COCIR Advancing Healthcare efpia MedTech Europe from diagnosis to cure EuropaBio Vaccines Europe An industry for healthy lives

Co-funded by the European Union

IHI: A public-private partnership



<u>Collaboration extends to</u>:

- Programming
- Financing
- Public and private partners collaborating in individual projects

Why participate in IHI?

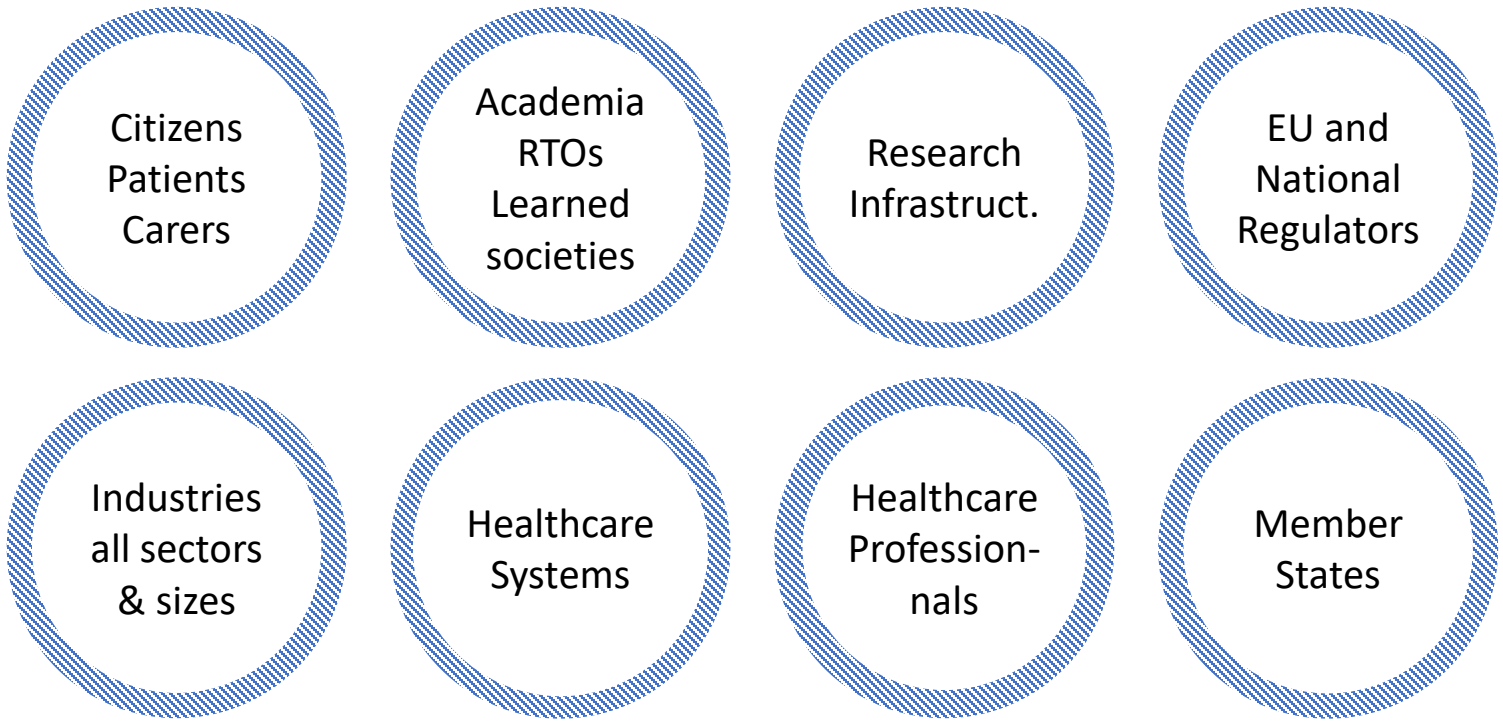
IHI's objectives are set out in the legislation creating IHI.

The general objectives are to:

- turn health research and innovation into **real benefits for patients and society;**
- deliver safe, effective health innovations that **cover the entire spectrum of care** – from prevention to diagnosis and treatment – particularly in areas where there is an unmet public health need;
- make Europe's health industries globally **competitive**.

Healthcare stakeholders

Potential participants to projects



What makes IHI different from regular HEU* calls

- IHI equally associates the EC and Industry in selecting the topics... unlike HEU where EC is the sole decider
- Each IHI project requires 50% of the budget from industry...unlike HEU where there is no minimum funding from industry
- IHI aims at delivering (direct and concrete) impact on the healthcare delivery
- The average budget of an IHI project is usually >15 M€, sometimes much more (ex: 60 M€)… unlike HEU projects with budget on average <15 M€

*Horizon Europe

COCIR
Advancing Healthcare