





Artificial Intelligence, Cybersecurity and Data Protection in Health: Current Trends in Europe and the Industry's Role and Contribution

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1. About COCIR



Industry sectors covered by COCIR



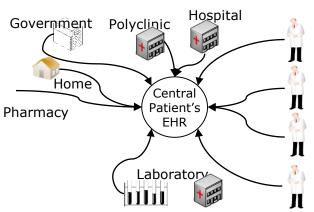
COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe



COCIR covers 4 key industry sectors:

- Medical Imaging
- Radiotherapy
- Digital Health
- Electromedical

Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle







COCIR at international level





2018: DITTA renewed NGO/NSA status with WHO

2016: DITTA MoU with the World Bank

2015: DITTA was granted a NGO status with WHO

2014: DITTA has official liaison with AHWP



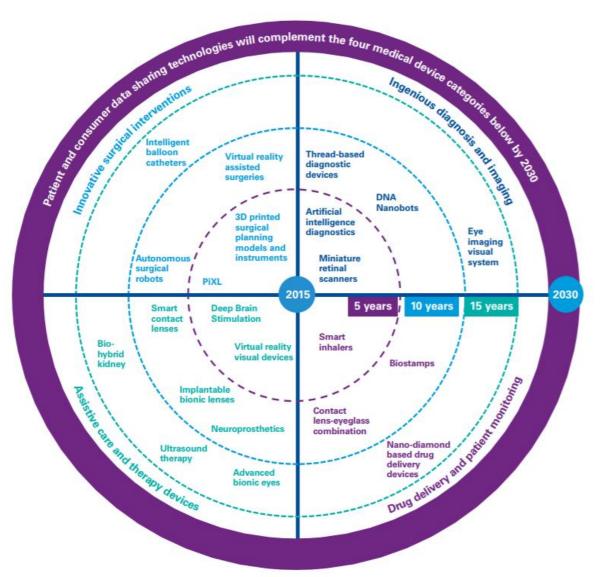




2. Digital Transformation of Health and Care



The future of health is data...medical devices 2030



Source: Medical devices 2030, KPMG 2018



Digital Transformation of Health and Care

European Commission strategy launched on 25 April 2018 with 3 pillars

- 1. **Citizens' secure access** to their health data, also across borders
- 2. **Personalised medicine** through shared
 European data
 infrastructure
- 3. Citizen empowerment with digital tools for user feedback and person-centred care





What EU citizens expect...

90% agree to access their own health data (requiring interoperable and quality health data)

80% agree to provide feedback on quality of treatments

80% agree to share their health data (if privacy and security are ensured)

Source: European Commission, 2018



...what industry can deliver

Empower patients to participate

Personal health record, Home health

Enable Informed Decision making

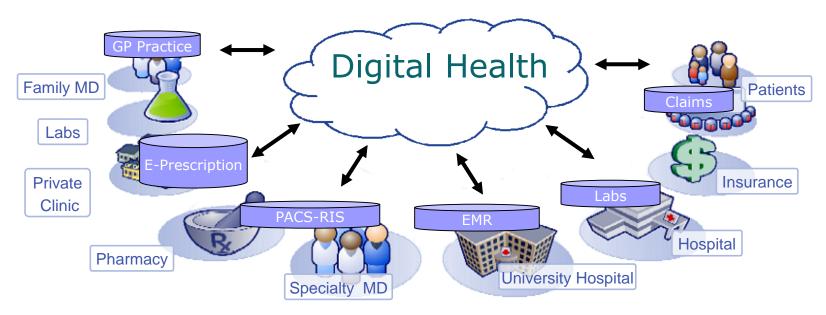
Reduce errors & redundancy

Optimize clinical staff productivity

Connect & collaborate

Improve access to healthcare

Enable Telemedicine





3. Data Protection



General Data Protection Regulation

 Most important change in data privacy regulation in 20 years!

 A regulation under EU law, it directly entered into effect in all Member States on

25 May 2018

Requirements

- Clear language
- Consent from users
- More transparency
- Stronger rights
- Stronger enforcement





What is next for the GDPR and health data?

- The GDPR is not applicable on the same basis in every European countries when it comes to conditions to process and control health data (art 9)
- A European Data Protection Board (EDPB) has been set up to ensure the consistent application in the European Union of the GDPR

A recommendation may be produced on how to treat health data.



4. Free flow of non personalised data



Regulation on free flow of non personal data

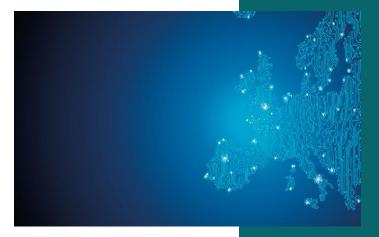
- Political agreement was reached on 22 June 2018 and official adoption should be finalised before the European elections in May 2019
- Abolishes data localisation requirements while making sure that competent authorities can access data for the purposes of regulatory control
- Addresses any data not relating to an identified or identifiable person, such as anonymised data and machine to machine data





Reflecting the realities of modern healthcare technologies

 Keeping equipment updated frequently relies on the capacity of appropriately-skilled, but often decentralised, support staff to be able to connect and access equipment across borders and jurisdictions



 For the large number of SMEs involved in providing digital health solutions and applications, these rules provide them with greater certainty on data storage, particularly cloud-based solutions







5. Industry Contribution



eHealth Stakeholders group

- COCIR participates in advisory group since its set-up (more than 8 years)
- Chaired by European Commission
- Task: Assist the Commission in the preparation of legislative proposals and policy initiatives in the digital health area

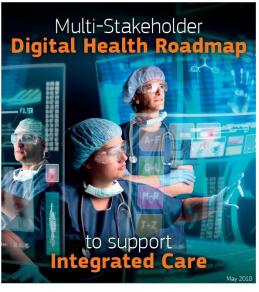




Digital Health Roadmap

- COCIR is a member of the Integrated Care Alliance
- Collaboration of industry, patients, carers, healthcare professionals and providers
- Goal: better health care coordination and to define specific activities in support of Integrated Care
- Latest publication in May 2018: Multi-stakeholder Digital Health Roadmap to support Integrated Care

















Our Industry's Focus

- Improve patient outcomes and survival rate via innovative diagnostics and imaging technologies
- Combine innovations with minimally invasive surgical techniques
- **Create benefits** for approx. 50-60% of cancer patients across Europe via innovative radiotherapy
- Transform healthcare systems in Europe and making the promise of 'big data' a reality
- Focus on patient centered approaches towards better integrated care, including e-health
- Contribute to Europe's economy, health, research and innovation ecosystems

COCIR and its members are committed to overcoming Europe's health challenges with innovative, cost-effective solutions, in close partnership with institutions and key stakeholders







Thank you for your attention!

www.cocir.org