





Track "Modernizing Identity & Trust in Healthcare"

Digital Transformation in Healthcare: industry trends and perspectives

Nicole Denjoy

COCIR Secretary General



TRUSTECH – 28 Nov. 2018
Cannes (France)



Table of contents

- 1. About COCIR
- 2. Digital Transformation of Health and Care
- 3. Data Protection
- 4. Non-personal data flows in the EU
- 5. Artificial Intelligence and Cybersecurity
- 6. Industry Contribution







1. About COCIR



Industry sectors covered by COCIR



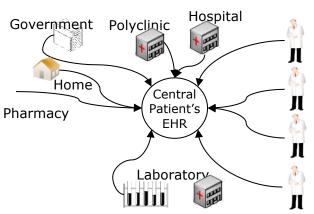
COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe



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 Members















































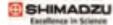




















NATIONAL TRADE ASSOCIATIONS MEMBERS











BELGIUM

FINLAND

GERMANY GERMANY









THE NETHERLANDS

HUNGARY









UNITED KINGDOM

SPAIN SWEDEN

TURKEY



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



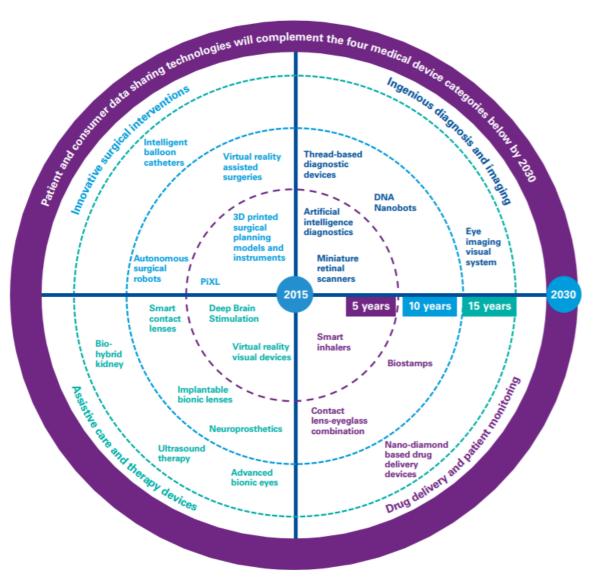




2. Digital Transformation of Health and Care



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



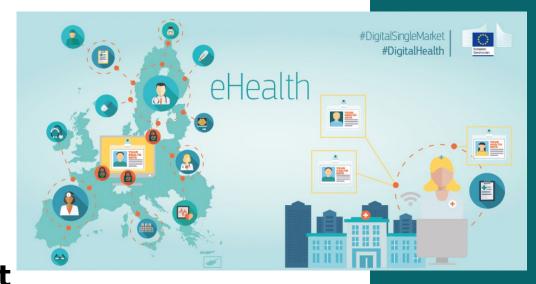
Source: Medical devices 2030, KPMG 2018



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

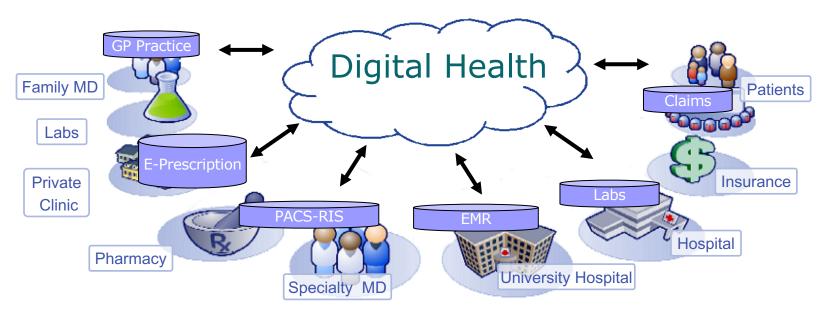
Reduce errors & redundancy

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. Artificial Intelligence and Cybersecurity



Artificial Intelligence: Several Initiatives...



European Alliance on AI



AI4P



Cybersecurity Package







Building EU Resilience to cyber attacks Reformed ENISA Cybersecurity Act EU cybersecurity Certification Framework Communication NIS Directive Implementation Rapid emergency response -Blueprint & Cybersecurity ecommendation Emergency Response Fund Cybersecurity competence network with a European Cybersecurity Research and Competence Centre Building strong EU cyber skills base, improving cyber hygiene and awareness

Creating effective EU cyber deterrence . Identifying malicious actors Stepping up the law enforcement response Stepping up public-private cooperation against cybercrime Stepping up political and diplomatic response Building cybersecurity deterrence through the Member States' defence capabilities

Advancing EU cyber dialogues Modernising export controls, including for critical cybersurveillance technologies Continue rights-based capacity building model Deepen EU-NATO cooperation on cybersecurity, hybrid threats

and defence

Strengthening

international cooperation

on cybersecurity

Promoting global cyber stability and

contributing to Europe's strategic autonomy in cyberspace



EU Cybersecurity Act



Our proposal

A voluntary European cybersecurity certification framework....



...to enable the creation of **tailored**EU cybersecurity certification **schemes** for ICT products and
services...

...that are valid across the EU











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





A 6-step Approach

1 2 3 4 5 6 CAPTURE ACCRECATE & SHARE COLLABORATE COORDINATE SMART CARE POPULATION HEALTH li₁tŸ All stakeholders in All stakeholders in Smart applications Multidisciplinary Delivery of integrated The acquired the care continuum the care continuum teams, including the care may begin, routinely support experience and capture may access, share, patient, formal and based on agreed caregivers and insights trickles informal caregivers care pathways patients, taking down to health care all necessary data aggregate and visualise meaningful and processes for across health and into account experts and health collaboration are data on a daily basis care settings. the changing policy makers, covering first medical medical, social and enabling them to set-up care but evolving to operational context. further focus on wellness and social Quality management outcomes and adopt care processes are in a VBHC approach place POLICY INCENTIVES SKILLS

1. Usability of EMP-L

navigation tools

Non-traditional

data capture:

medical devices.

wearables, social

Patient Reported

media, -omics,

3. Cloud and Mobile-

Outcomes

ready tools

data capture and

INTEROPERABILITY DATA PROTECTION

- 1. Sementic Interoperability for data and workflows
- 2. Standards
- 3. Natural Language Processing
 - 4. Identity management and patient consent
 - Visual integration of external data sources
 - 6. Data sharing platforms

- 1. IT support for the establishment of teams and collaboration between team members
- 2. Bi-directional 3. Visual integration instantaneous communication between team members
 - tools and apps 4. Gamification to engage citizens and patients

1. Distributed

and dynamic

2. Patient-specific

in daily used IT

care plans

workflows and

associated tools

5. Telehealth

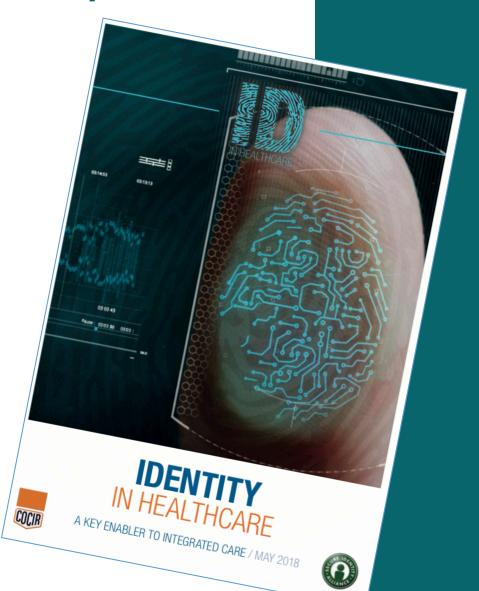
HEALTH TECHNOLOGY ASSESSMENT

- Big Data Lakes (from diverse data sources)
- 2. Deep Machine Learning (bottom up)
- 3. Rule based decision support (top down)
- Knowledge sharing platforms
- Big data analytics, including risk. stratification tools
- 6. Impact assessment tools

Partnership with SIA on Identity in Healthcare

What we need:

- Stronger policy regarding ID
- Leverage eIDAS for crossborder healthcare
- 3. Raise awareness regarding GDPR and ID
- 4. Open to innovations and to various technologies that can be combined





Industry Perspective on AI

- What do we mean by AI in Health and Care?
 - CADe, QIT, CDS, CADx*
- Why is it important?
- 7 Focus areas to play successfully
 - 1. Build awareness with Innovators/early adaptors/KOLs
 - 2. Support and **enable access** to massive amount of Imaging Data
 - 3. Build a **sustainable G2M** Modell by Provisioning AI-plattforms integrated into clinicians daily routine workflow vs. stand alone applications
 - **4. Drive adoption** by impact driven (COF-Perspective) use cases
 - 5. Support deployment by **robust Legal framework**
 - 6. Consider latest **Regulatory Framework**
 - 7. Apply **Ethical Framework**

¹ * CADe= Computer Aided Detection, QIT=Quantitative Imaging Tools, CDS=Clinical Decision Support. CADx= Computer Aided Diagnosis,



Other COCIR Publications





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