Sustainable Competence in Advancing Healthcare

# From health policy to practice

Medical imaging as an example for improving patient outcomes through technology adoption

*European Parliament – 6 June 2018*

## Innovative technologies bringing benefits to patients in a changing regulatory environment

***Nicole Denjoy***
*COCIR Secretary General*

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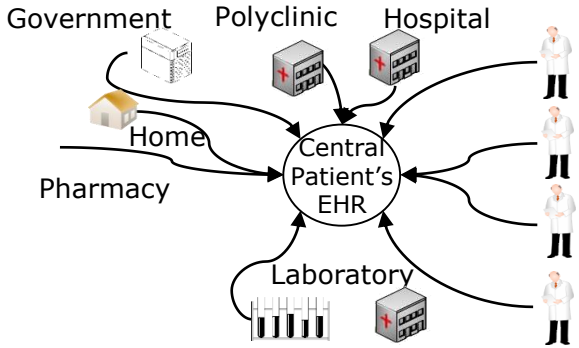
# Industry sectors covered by COCIR

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
- Health ICT
- Electromedical


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




# COCIR at international level

# COCIR partnership with ESR


COCIR has a long standing cooperation
with ESR since 2008

- Joint sessions at ECR
- Eurosafe imaging (Age Profile)

# 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**

# Technology in Healthcare is developing fast

## Diagnostics

- Faster, accurate imaging
- Molecular imaging
- Minaturisation/portability
- Point of Care diagnostics
- Therapy selection/monitor

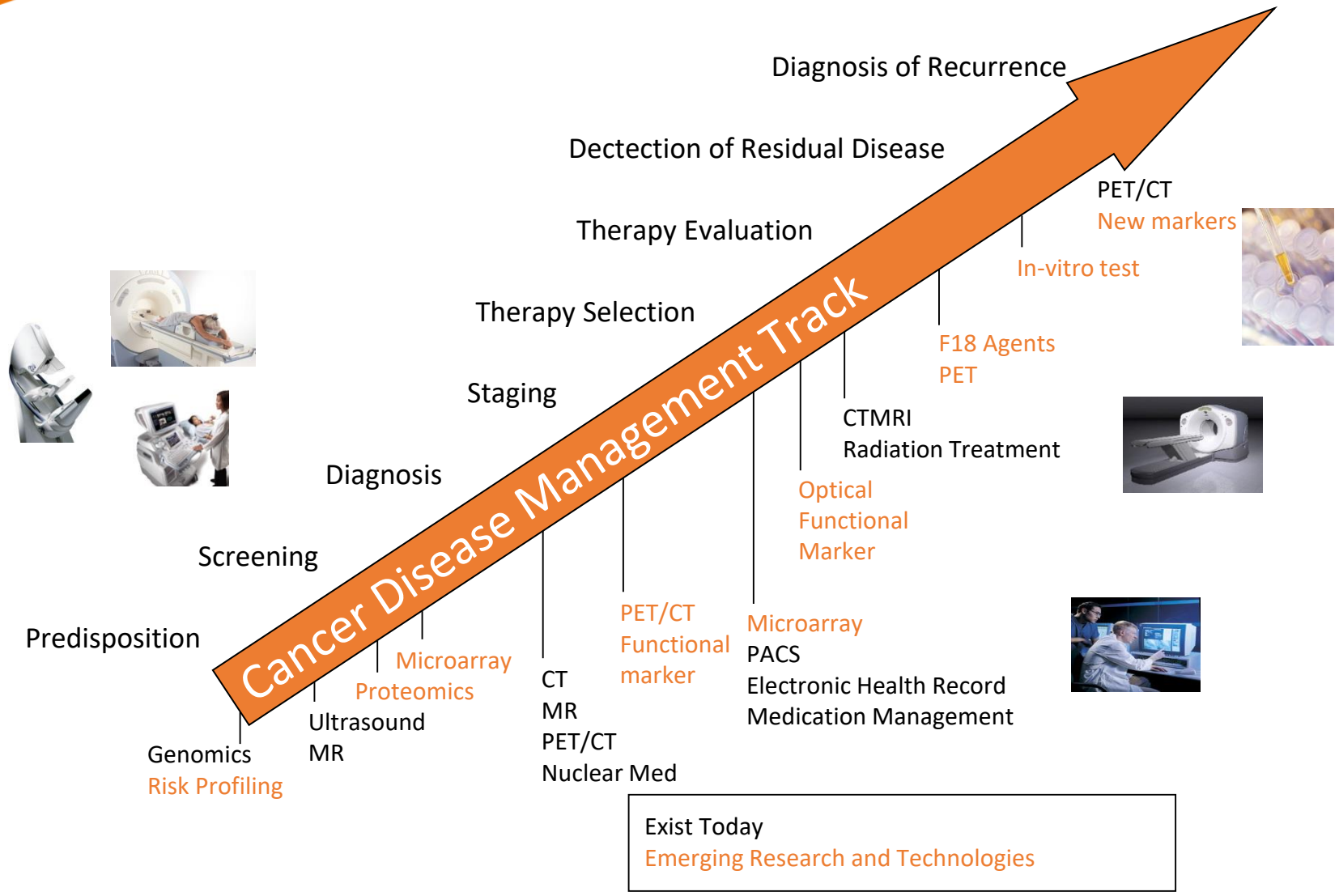
## Biotech & Genomics

- Targeted therapy
- Proteomics/DNA
- Biomarkers
- Rapid screening tools
- Vaccine development

## IT & bioengineering

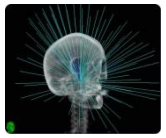
- eHealth/Telemedicine
- Mobile solutions
- BioSensors
- Computer Aided Diagnostics
- Patient monitoring

# Cancer Care Pathway: Continuous Innovation for better Patient Outcomes



# The potential of Radiotherapy (RT) in Cancer Treatment

## Less invasive & more accurate


Radiosurgery



Intraoperative Therapy


Robotic Surgery

## RT & Digital Frontier: Combined Innovation

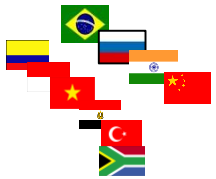

Big Data


Decision Support


Tele-Medicine


Mobility

## Radiotherapy, a cost effective solution

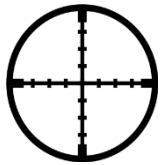

Cost of Care


Emerging Markets Growth


Education Gaps

Regulatory Oversight

## RT Impact on Personalized Medicine


Targeted Therapies


Molecular Imaging


Patient Self-Care (Equicare)


Genomics

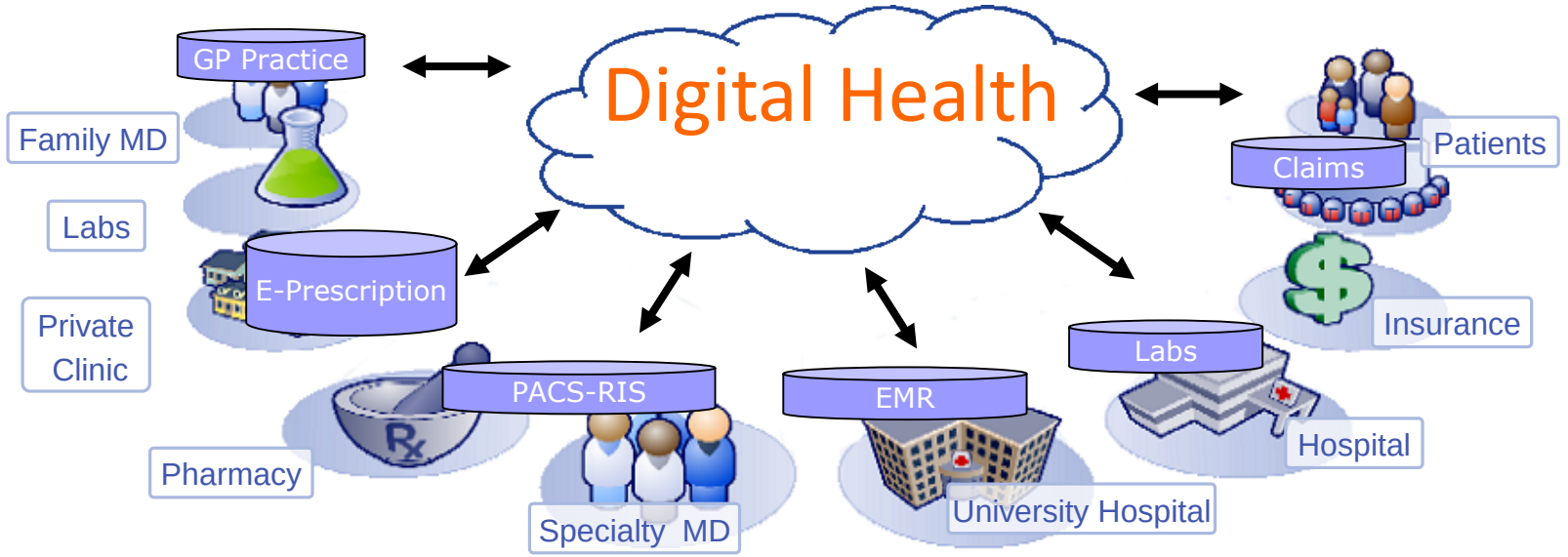
# The Value of Digital Health

**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

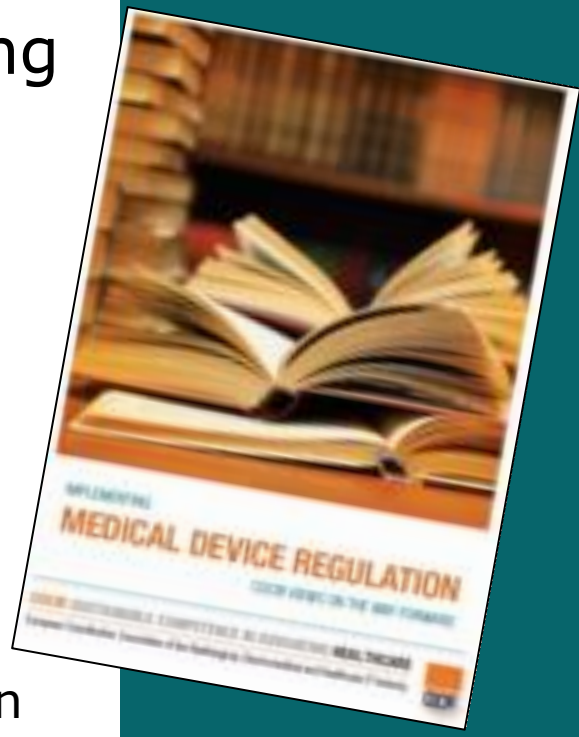


# Sum of all Regulations impacting our industry

| DG GROW | DG ENVI | DG JUSTICE | DG CNECT | DG SANTE | DG ENER |
|---|---|---|---|---|---|
| • Medical Device Regulation (May 2020)<br>• Machinery Directive (December 2009)<br>• Radio Equipment Directive (June 2017) | • RoHS Recast (July 2011)<br>• WEE Directive (February 2014)<br>• REACH (2007) | • GDPR (May 2018) | • E-Privacy Regulation (on-going) | • HTA Regulation (on-going) | • BSS Standards (February 2018) |

# Implementing Medical Device Regulation

COCIR is currently engaged in 26 different EC/MSs Working Groups and informal Task Forces to provide expertise and input to the implementation process




**Opportunities**

- Further harmonisation in the European internal market
- Centralised database Eudamed

**Challenges**

- Expected delays in implementation and guidance due to lack of resources in European Commission and Competent Authorities (e.g. sufficient clinical evidence for clinical evaluation)
- Possible increased time-to-market because of new requirements (e.g. medical device software, clinical evaluation and investigations, post-market surveillance)
- Foreseen delays for harmonised standards under MDR
- Doubts on availability and capacity of Notified Bodies

# COCIR supporting MFF on-going discussions

***What is needed in the next Multiannual Financial Framework and the related funding programmes (Horizon Europe, Digital Europe, Cohesion and Social+?***

- A **coherent** funding and investment framework along the innovation cycle, including deployment of health technology solutions
- **Increased funding** for the medical and digital health industry
- **Early Industry involvement**: bring indispensable private capital and create economic and societal impact
- **Need a strong R&D&I position for Europe in the world**, with increased financial support in Horizon Europe
- Need political support for cross-sectorial initiatives, including Digitising European Industry (DEI) policies
- **Public-private partnerships** (contractual PPPs and JUs like ECSEL) that better address private sector needs

# How to provide innovative technologies in a changing regulatory environment?

- **Consistency and predictability of the regulatory environment**
  - Medical technology industry is striving to adapt to a range of regulatory changes in short order – making it harder to maintain a high rate of innovation

- **Smart Regulation**
  - Avoid overlaps, adhere to principle during implementation, evaluate based on true indicators, involve industry earlier in the process

- **Active support for research, development & innovation**
  - Sufficient funding  in next Multiannual Financial Framework and related spending programmes