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COCIR's role in advocating Real World Evidence What's Working?

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1. COCIR Outline



What does COCIR do?



COCIR is a non-profit trade association, founded in 1959, representing the medical technology industry in Europe



COCIR covers 3 key industry sectors:

- Medical Imaging
- Electromedical
- Health ICT

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





With offices in Brussels and in China, COCIR promotes the use of advanced medical and ICT technology towards seamless care delivery and shared knowledge

to build a better world with improved access to affordable, quality and safe healthcare



COCIR Company Members

COCIR COMPANY MEMBERS

































































COCIR National Trade Associations Members

NATIONAL TRADE ASSOCIATIONS MEMBERS





















SWEDEN







COCIR's Focus: improve market access

- Provide COCIR's members with competence towards policy makers in Europe and outside
- Contribute to sustainability of healthcare systems through integrated care approach
- Promote Research and Innovation as a key enabler for economic growth
- Drive global regulatory convergence (registered once, accepted everywhere)
- Optimise use of International standards
- Push for national and regional deployment (eHealth)
- Pro-active in Green Technology (Eco-Design)



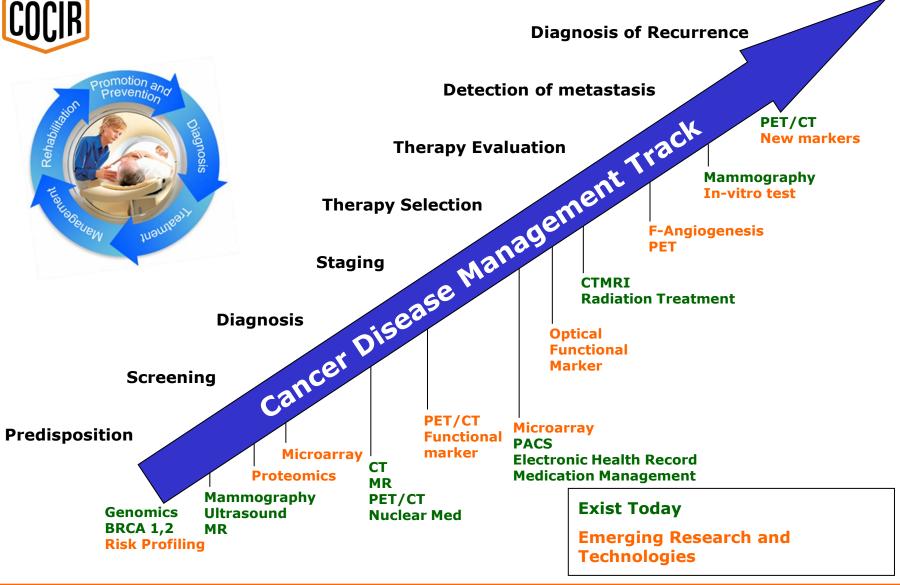




2. Innovation in Medical Technologies

COCIR

Technologies across almost the entire patient pathway





Innovation in Medical Technology

Diagnostics

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

Biotech & Genomics

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

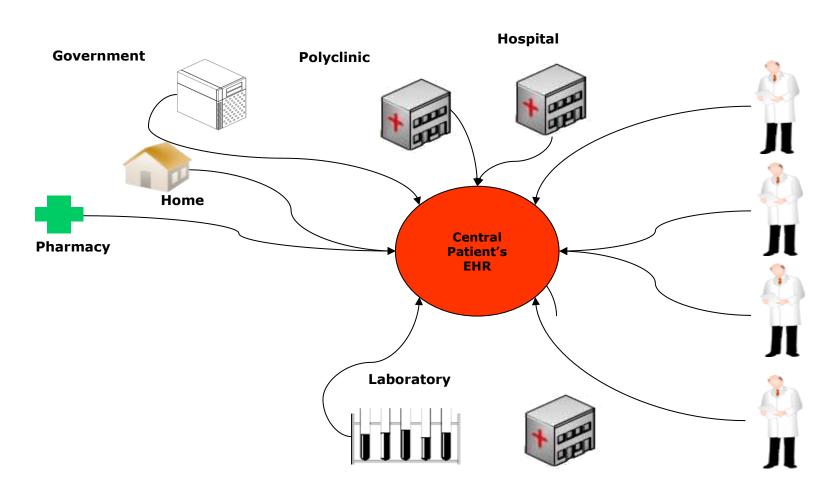
IT & bioengineering

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





Healthcare IT facilitates delivery of higher COCIR quality and more efficient care









3. COCIR's focus on Real World Evidence



COCIR's channels on Real World Evidence

- HTA: COCIR is actively engaged in EU's 'Joint Actions' through EUnetHTA since 2010 to introduce a pan-European HTA network (... to enable patients' better access to innovative medical technologies Article 15 of X-border Healthcare Directive) and in AdHopHTA
 - → Work Packages
 - → Stakeholder Forum
 - → Development & dissemination of policy recommendations on behalf of manufacturers



- Data Protection Regulation: Policy recommendations on use of Health Data
- Big Data: COCIR initiatives on Big Data & eHealth
- Research & Innovation: Focus on Horizon 2020



Use of Real World Evidence for HTAs

- HTAs developed on pharma model
- Randomized Controlled Trials (RCTs) 'the norm' to demonstrate safety & efficacy of drugs → required for regulatory approval
- Non-drug technologies have many differences
- RCTs often not appropriate to demonstrate full value (clinical, economic, organizational)
 - → need to consider other methods of evidence demonstration to quantify & qualify the full value of non-drug technologies



Recommendations on the General Data Protection Regulation(GDPR)

The Healthcare Coalition on Data Protection















The Coalition endorses the goals to:

- 1. Harmonise the regulatory environment on the protection of personal data in the UE
- 2. Strenghten the protection of personal data while maintaining the free flow of personal data
- 3. Provide exemptions for health and research purposes
- ... and proposes recommendations to facilitate healthcare and health research for the benefit of patients without
- restricting the sharing of health data
- delaying innovation
- creating legal uncertainty
- increasing compliance costs



Real World Evidence - What's Working?

→ **BIG DATA** – databases used for study purposes





http://issuu.com/cocir/docs/14005.ehealth_toolkit_2014_issuu

→ 'Small data' – collection studies to qualify & quantify the benefits of a technology practice



COCIR efforts on Horizon 2020

 COCIR is maturing a Strategic Research Agenda in the context of Horizon 2020 which includes an element on "Health Technology Assessment Methodology and Infrastructure"









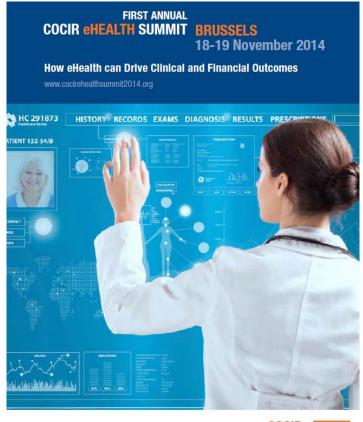
4. Important information from COCIR











COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

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







Thank You