Sustainable Competence
in Advancing Healthcare

Developments in Europe on Artificial Intelligence and Software

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1. About COCIR

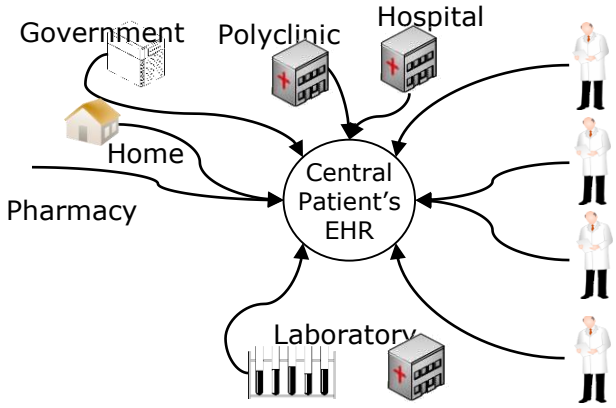
Industry sectors covered by COCIR

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

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

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. Artificial Intelligence

What is Artificial Intelligence?

Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals.

Source: European Commission, 2018

A European approach to Artificial Intelligence

1. European Commission **Communication** in April 2018

***"Like the steam engine or electricity in the past, AI is transforming our world, our society and our industry**. Growth in computing power, availability of data and progress in algorithms have turned AI into one of the **most strategic technologies of the 21st century**. The stakes could not be higher. **The way we approach AI will define the world we live in**. Amid fierce global competition, **a solid European framework is needed**."*

2. European Commission created a **High Level Expert Group on AI including 2 working groups (1) on ethical framework (2) on policy and investment strategy**

=> Healthcare is identified as one of the most crucial areas of application

Investment in Artificial Intelligence

The European Union has decided <u>to invest heavily in AI during its next budget cycle</u> 2021-2017

- Several billions for **research, development, and innovation**

- Up €2.5 billion for **scaling up and deployment** of AI technologies

Ethics and Artificial Intelligence

- COCIR created in June a dedicated Focus Group on AI
- COCIR participates to various initiatives:

1. Newly set-up by the European Commission: a **European AI Alliance**

   Contributes to drafting of AI Ethics Guidelines by European Commission and dedicated experts from key stakeholders

2. **AI4People**
   - Think Tank organization supported by the European Commission and the European Parliament
   - first global forum in Europe on the social impact of AI and annual conference in November in Brussels in which COCIR will speak
   - Goal is a set of ethical guidelines for a "good AI society"
   - Includes European Commission, European Parliament, industry and civil society

European Medical Device Regulation and AI

Many questions to answer:

? After continuous-learning software is placed on the market, will it continue to learn and refine its internal model? Or is it locked at the time of launch?

? Does the changed algorithm change the intended purpose?

? Does it require additional clinical evidence?

? How much human decision-making is involved?

? Does the system make suggestions that humans can disagree with, or does the system make decisions on its own?

3. Classification of software

What's new for software under the MDR?

New

- MDR also applies to certain **products without medical purpose** (so-called Annex XVI devices)
- Introduction of **Classification Rule 11**
- Medical software is subject to the MDR when offered to a person in the Union regardless of whether it operates in the **cloud or is based on a server** outside of the European Union
- An **app store** could now be considered a distributor
- **General Safety and Performance Requirements** 14.2 and 17 that are specific to software and require to manage
  - (1) security
  - (2) the impact of the IT platform it is installed on

What classification rules to consider?

Rule 10 Active devices for diagnosis or monitoring

Rule 11 Software, alone or in combination

Rule 12 Administration or removal of substances

Rule 13 All other devices

Latest developments

- COCIR participates to the EU **Software Classification Task Force** currently chaired by Authorities from Germany
- **Goal**: guidance on medical device software qualification and classification
- Expected publication **beginning of 2019**

Current status of Task Force discussions

- Scope of the guidance includes **Medical Device Software** (both independent software and software that drives or influences a hardware device)

- **IMDRF risk categorization scheme** will be applied to interpret Rule 11 Paragraph I with the IMDRF categories translated into the MDR risk classes

Results: Medical Device Software will be classified to a minimum IIa and systematically up-classified in comparison to the Medical Device Directives including the possibility of class III software

Open questions for industry

? Exact **scope and definition** of Medical Device Software still needs to be further clarified

? Interpretation of **IMDRF Framework for Risk Categorization** is not yet clear on all aspects (for example, certain conditions for the qualification of the healthcare situation)

? What will be the impact for **medical device software in class III**, especially the requirement for a clinical investigation?

4. Clinical evaluation of software

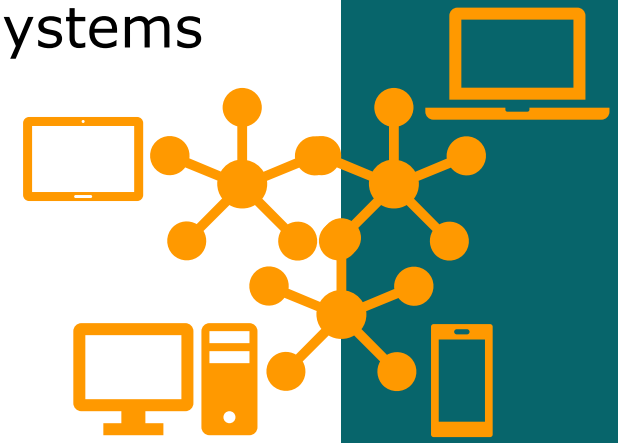
What's new with the MDR?

New

- Introduced concept of **Interoperability** to devices including software:
  - the ability to exchange information and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or
  - communicate with each other, and/or
  - work together as intended.
- Interoperability (and compatibility) must be reliable and safe
- **Software change evaluation**: new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability
- Possibility of **class III software** requiring a clinical investigation

Software presents unique challenges….

- **Increasingly complex**, with analytics that provide a higher level of clinical decision support
- Operates in a complex socio-technical **environment**
- Often part of **larger systems** that must operate in a unified manner
- Often depends on other **commercial off-the-shelf (COTS) software** and on other systems and data repositories for source data
- **Rapid** development cycles
- **Frequent** changes
- Updates delivered by **mass and rapid distribution**



…and opportunities for clinical evaluation

Software has the **capability of communicating**, compared to physical medical devices

The data used to set the baseline clinical evidence can be easily and continuously **acquired from the field** to confirm or adjust the clinical performance and safety of the device

Software can be **continuously enhanced**

Software **evolves** based on user feedback

Embrace real-world data to drive real-world evidence

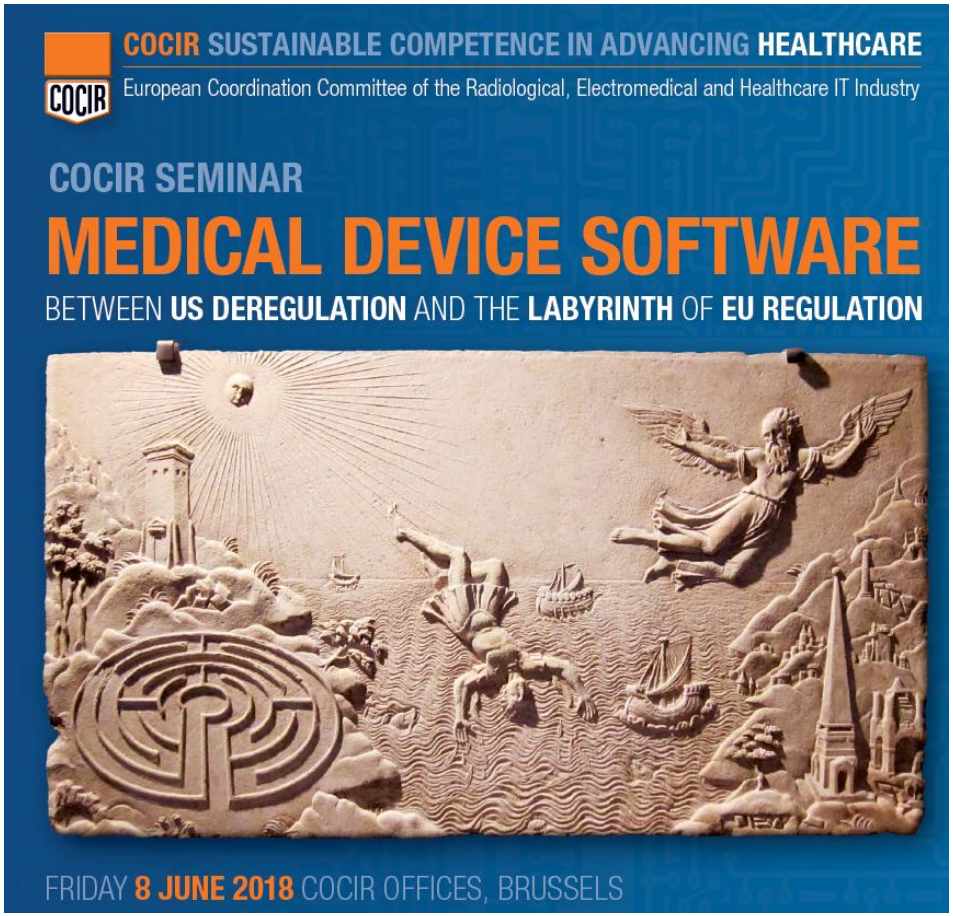
- There is a **need for balance** between constantly testing and validating software and the clinical benefits of using the software
- The manufacturer must do a reasonable job to **identify and address any outstanding safety issues** before the device goes on the market, but it would be impossible task to resolve every possible issue since the testing environments for investigational devices are so limited
- Close interaction between software versions and user feedback requires to **continuously reevaluate** the clinical performance of software medical device.
- **Real world performance data** may provide evidence that the analytical or clinical validity of a software is superior to the performance measures initially evaluated by the manufacturer

Are clinical studies necessary?

- The **impact of software on patient outcome** is usually indirect
- **Treatments** are often given as combination treatments and the physician normally decides how to treat, not the device
- **Normal Conditions of Use** of the software often differ significantly from the Ideal Conditions of Use of a Clinical Investigation
- Clinical studies are not **ethically justified**, if the clinical benefits can be demonstrated by the analysis of available clinical information

Latest developments

- COCIR participates to EU **Task Force on clinical evaluation of software**
- Task Force Chaired by Authorities from Sweden
- **Goal**: Guidance for clinical evalution of software under the Medical Device Regulation
  - Scope aligned with draft guidance on classification of software
- **IMDRF N41** (Clinical Evaluation of Software as a Medical Device) to be used as driving principle



Stay tuned for the second edition!

Thank you for your attention!

www.cocir.org