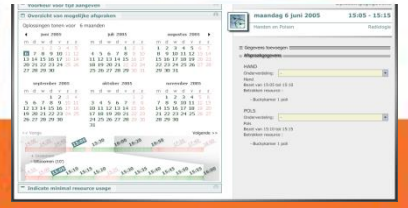
COCIR

Sustainable Competence in Advancing Healthcare



EUnetHTA / Medical Technology HTA Expert Meeting

Friday 16 October 2015, Brussels

HTA FOR MEDICAL DEVICES

expectations and limits of the EU cooperation on HTA, the view of COCIR

COCIR HTA Task Force

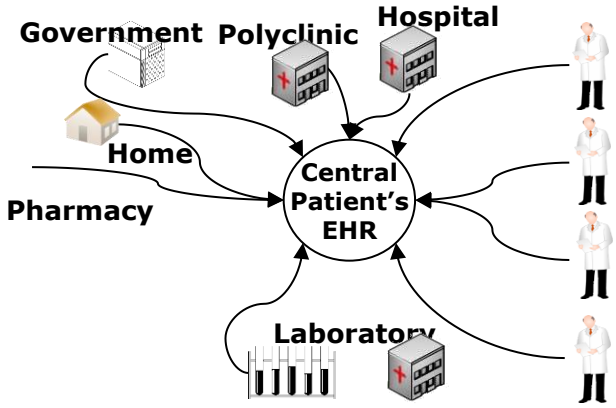
Industy sectors covered by COCIR

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
- Electromedical
- Health ICT

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



33 Member Companies

14 National Trade Associations

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14:00- 15:00 session

"Views on successes, value & impact of JA2 collaborations for non-pharma technologies"

COCIR's experience from JA2

1. COCIR believes that significant development towards HTA collaboration has been made during JA2

2. For example: a common understanding of value, evidence requirements, methods, templates, guidelines, stakeholder involvement and [some] recognition of the need to evaluate different medical technologies differently have all developed during JA2

3. Understanding of the diversity of HTA requirements and capabilities both ***within*** and ***across*** MS has also increased significantly

COCIR' s lessons learnt from JA2

1. As 'stakeholders' we have not felt like true partners - but rather given the opportunity to input from time to time
2. Often there was little opportunity to discuss our views/input, and often there was little evidence that our input was taken into consideration. So, we were asked but nothing appeared to happen
3. When reviewing documents we need to be able to share & collect input from colleagues/experts within our own organizations. This is critical to ensure we provide the best possible input. The confidentiality agreements must be revised accordingly
4. There must be a clearer link between "common" HTA activities at the European level & national decision making, with all relevant stakeholders actively participating. Without this it is hard to see the value of further "common" HTA activities at the European level

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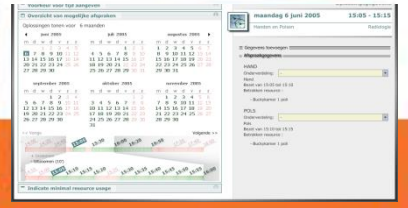

15:30-16:30 session

"Teaming Up for Value - views on how HTA cooperation could be of value and could be impactful in the next JA3 and beyond"

COCIR's expectations regarding future cooperation on HTA

1. COCIR agrees & supports *more* cooperation with industry on HTA

2. The value of 'medical technologies' to healthcare providers, needs to be evaluated *differently* from pharmaceuticals & other medical devices

3. COCIR believes strongly that a *partnership* is the best way to achieve the stated goals of HTA *and* cooperation – to expedite the supply of effective & cost-effective technologies for the benefit of patients

Why COCIR agrees & supports *more* cooperation on HTA

Our Objectives:

- To expedite the transfer of effective & cost-effective 'medical technologies' to benefit patients, and improve the efficiency of healthcare provision
- To avoid duplication of effort → increase efficiency
- To reduce uncertainties:
  - → provide more consistency of assessment in terms of information requirements, methods, timelines, etc)
  - → potentially reduce differences of opinion regarding the value of technologies between member states

Need for a broader perspective

Modern 'medical technologies' can provide different types of value:

- **Clinical** → patient outcomes
- **Organizational**:
  - Increasing throughput
  - Reducing downtime
  - Etc

→

- **Saving scarce resources**
- **Improving efficiency of healthcare**

- **Societal:** reduced absenteeism from work/increased productivity at work→ improving the economy

HTA of technologies such as diagnostic imaging, monitoring, healthcare IT, etc need to consider the full value of the technology and not discriminate against products that provide organizational and societal value

Integrated care brings significant benefits to patient outcomes

Today

1920

Importance of IT support

COCIR call to HTA Network

1. Need trust in Industry. Industry is part of the solution and not part of the problem. Observer status is not enough and request was made to have a seat at HTA Network

2. Don’t mix CE Mark and HTA

3. Need effective coordination between Member States to increase efficiency and limit complexity

4. Better coordination between various initiatives (e.g. AdopHTA)

COCIR believes strongly that a *partnership* is the best way to achieve the stated goals of HTA *and* cooperation – to expedite the supply of effective & cost-effective technologies for the benefit of patients

From an industry perspective…

- We research, develop, supply & support the vast majority of 'medical technologies' brought to market. We have the technical specialist knowledge.
- 'Medical technologies' are developed hand-in-hand with experts & opinion leaders, as well as reps of routine clinical practice. We work hand-in-hand with healthcare providers.
- Manufacturers support & often further develop technologies over the entire lifecycle - adapting & developing applications in step with advancements in medical practice
- Manufacturers invest in market adoption, providing training, awareness, guidelines, case studies, best practice, etc
- Industry has a valuable contribution to "bring to the table" of HTA cooperation

Feed-back to DG Sante (1/2)

Question	COCIR Response
1. Are you as a stakeholder content with the current situation as regards your representation in the HTA-Network? Please suggest possible improvements and alternatives.	Overall we are not content and we believe COCIR should have a 'seat at the table' of the HTA-Network. We have already expressed our concerns and sent a letter to Tapani Piha from DG SANTE in February 2015 requesting the possibility to have COCIR represented and participating in HTA network (not indirectly and not enough to be just consulted occasionally)
2. Status of Stakeholders in JA3. Considering the different options of participation presented below, what is your view regarding stakeholder engagement in the JA3? *(For more details, see the attached document)* - Beneficiary - Subcontractor - Collaborating Stakeholder	The best option for COCIR would be a Collaborating Stakeholder. Our focus is not to receive money to participate to meetings but be able to directly contribute on the contents.

Feed-back to DG Sante (2/2)

1. Value of the EUnetHTA Stakeholder Forum? How do you see the present layout and value of the SF and how could it be improved?	In our view the SF is currently seen as an <u>information exchange</u> with a limited representation of EC, EUnetHTA (management + chairs of Work Packages), with limited time available to discuss/debate substantive issues, develop fresh thinking, or discuss different alternatives (thus lacking strategic discussions that we believe are/should take place at HTA Network). <u>Weakness at level of SAG:</u> The real debate/discussion/exchange of ideas from different stakeholders leading to actions should occur in the SAGs of the various work packages. This is where we (and other stakeholders) believe JA2 has been dysfunctional – with plenty of input being received from various stakeholders but no real dialogue or debate, or tangible evidence of ideas being taken on board, or anything incorporated or changed. This is where we believe there needs to be a different way of working in JA3. Our proposal : - On <u>operational level</u> we could maintain the SF as is with agendas having: o Process discussion o Particular issues for Pharma o Particular issues for Medical devices With enough time to discuss substantive issues Periodicity could be 4 times/year 2 F2F/2TCONs) - On <u>strategic level</u> we would like to interact with HTA Network (see point above) – systematic space for Medical devices in the 2 F2F meetings per year - <u>For discussions at SAG levels:</u> allow discussions via TCON or others mean better than just exchange of correspondence
2. Contribution to the production of joint assessments and our financial needs. What are our financial needs for engaging in the production of assessments in JA3?	Our understanding is this applies to stakeholders such as payers, providers and patient organizations but not industry associations. Therefore our answer to this question is "not applicable" for COCIR. We support that other stakeholders cited above need financial support as it remains important to keep them at the table to have true multistakeholder discussions and inputs.

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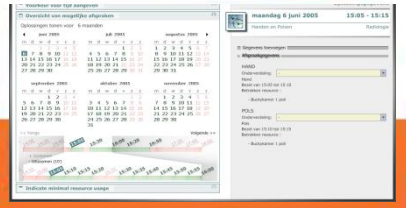
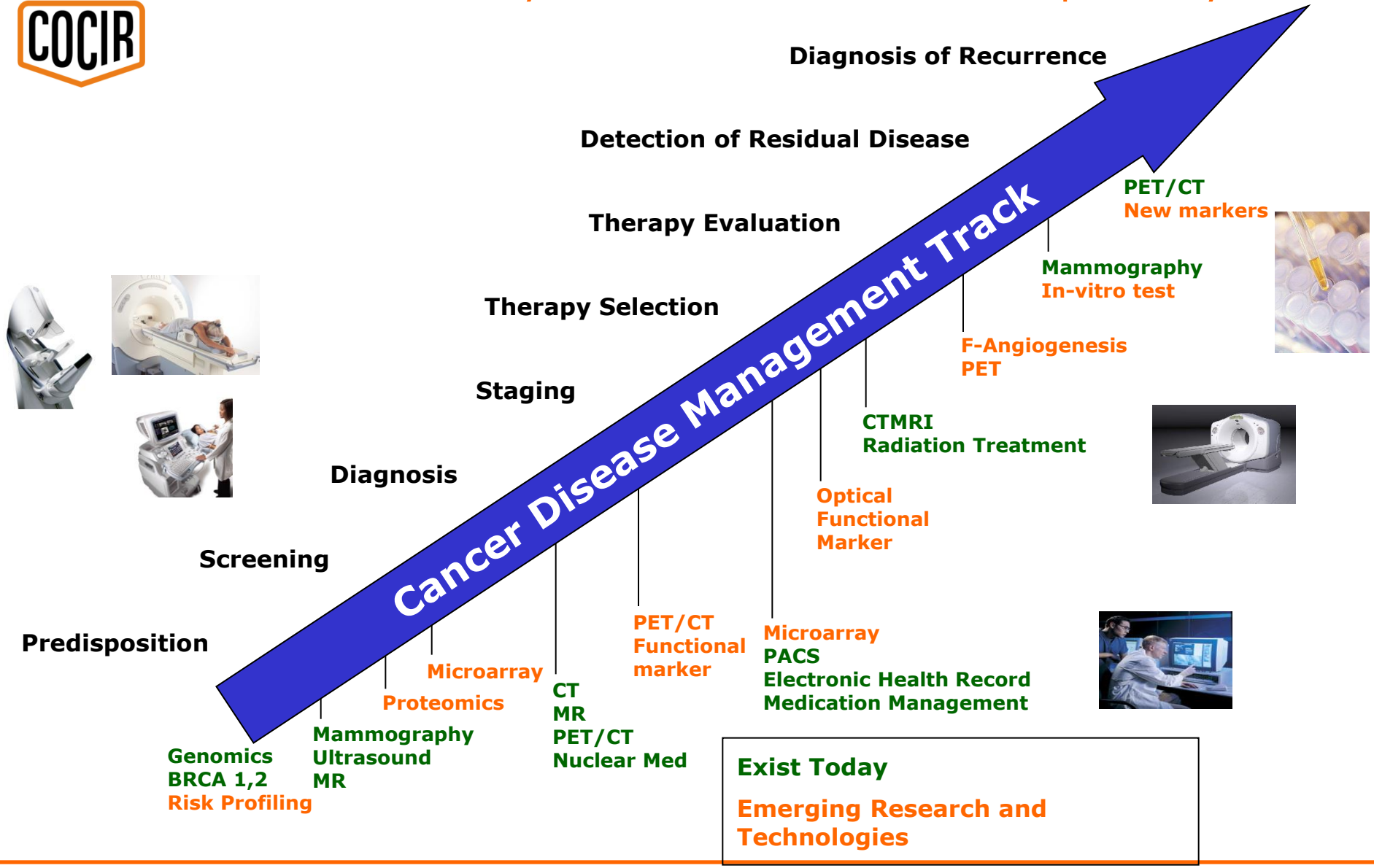


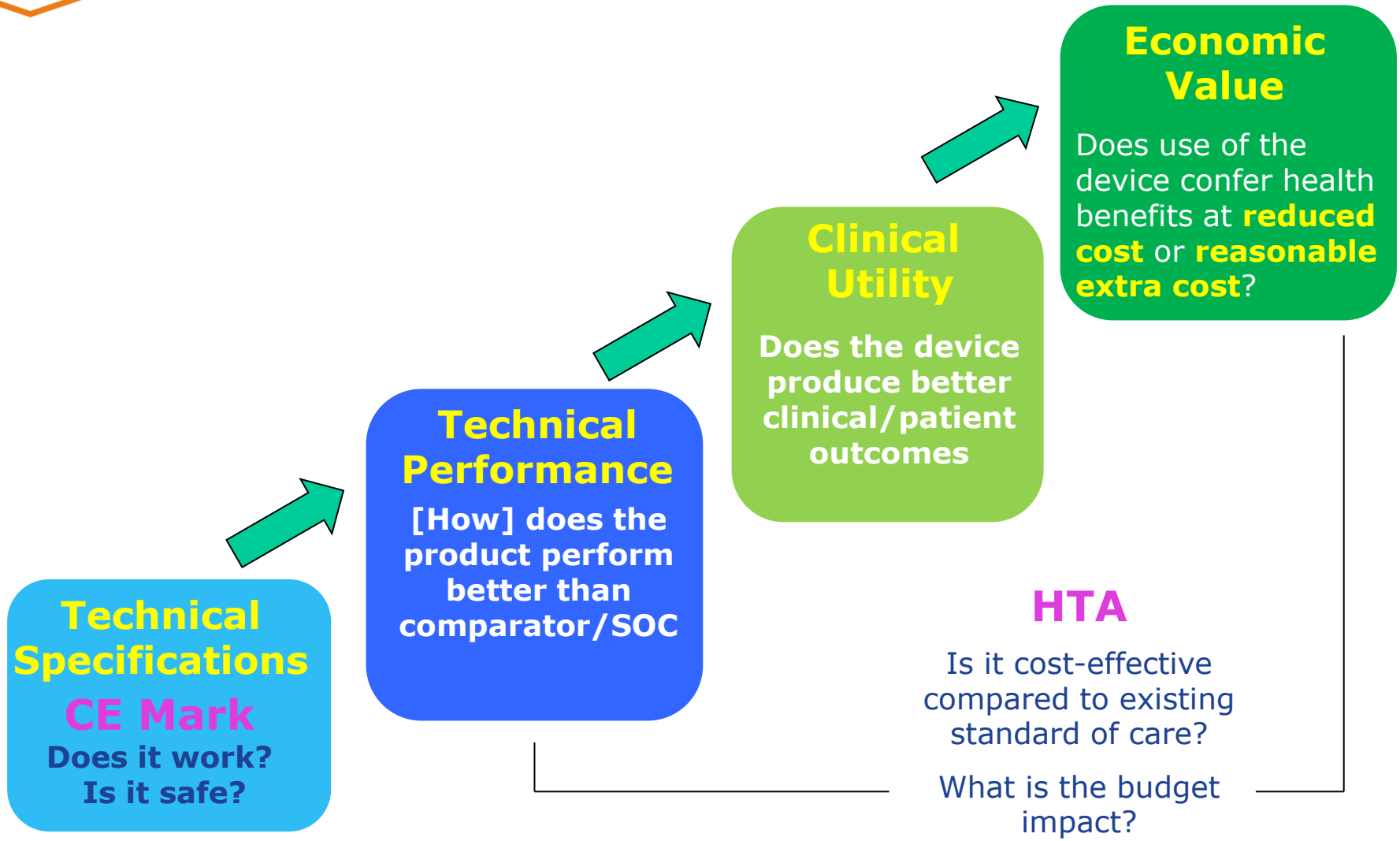
Thank You – Any Questions?

An example:

COCIR Industry covers the entire disease pathway



Differentiation between CE Mark and HTA



…and have different business models

- Different scale of product: e.g. DaTSCAN peak sales $10's of millions, blockbuster drug $billion, 100x more
  - implication: much less to invest

- Limited or non-existent IP – impact of outcomes often shared by manufacturers
  - implication: disincentive to invest heavily in evidence generation

- Medical imaging is not reimbursed by product or often even not by technology but by procedure [despite lack of comparative data]
  - implication: disincentive to invest heavily in evidence generation if other manufacturers can benefit

These commercial considerations deter significant up-front investment in expensive studies. Nevertheless innovative Medical Imaging & Health ICT products offer significant benefits to patients, providers and payers

Not only technologies need to be assessed but the entire process

- **Other elements should be considered besides clinical effectiveness:**
  - Quality
  - Access
  - Patient experience
  - Organisational considerations
  - Ethical considerations

- **Examples of other models recognised for health ICT:**
  - MAST (Model for Assessment of Telemedicine applications): a multi-disciplinary method used to assess telemedicine in Renewing Health project. Although designed for telemedicine innovations, it can be applied to a wide range of eHealth services.
  - PDSA (Plan, Do, Study, Act): a quality improvement method which uses an iterative approach to improve the performance of a process (enabled by technology) until it produces the required outputs.

The aim of these new approaches is to deliver measurable and sustainable improvements