



4th HTA Network Meeting

Monday 23 March 2015, Brussels

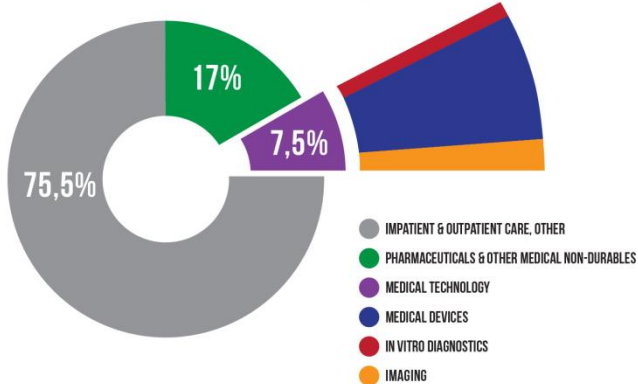
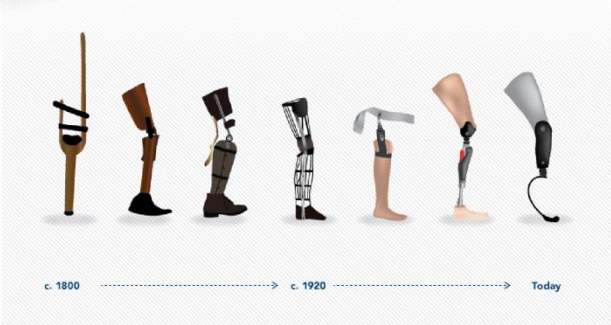
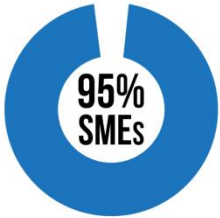
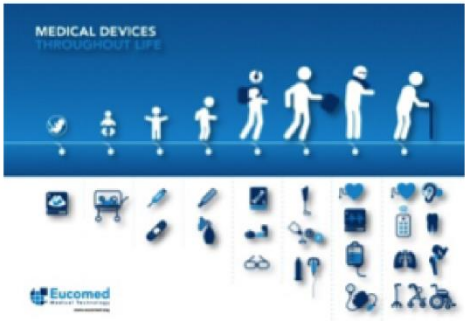
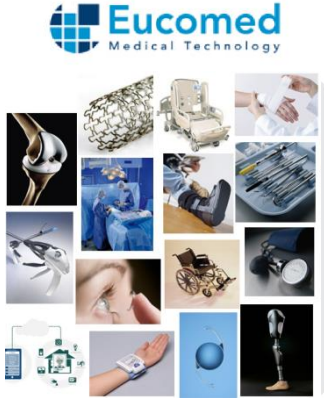
HTA for Medical Devices -
expectations and limits of the EU cooperation on HTA,
the view of med tech Industry

*Serge Bernasconi, CEO Eucomed and CEO EDMA, members of MedTech Europe
Dr Geoff Wilson, COCIR HTA Task Force Leadership*

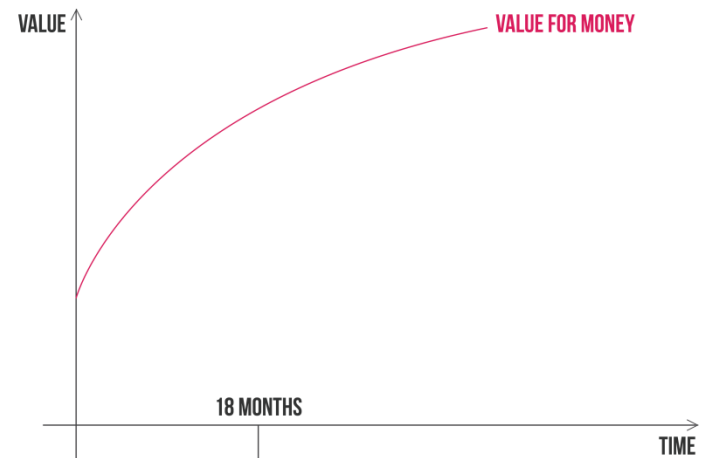
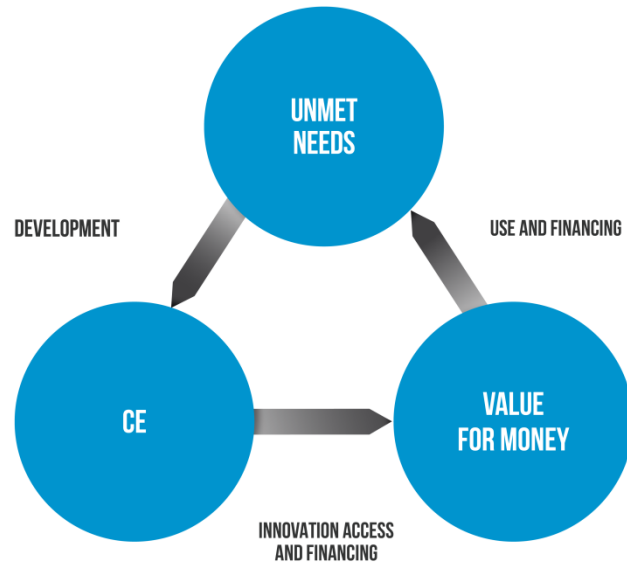
Medical Device and IVD Industry Characteristics

1. Medical Technology saves lives and transforms people's health and well-being, from diagnosis to cure

2. Medical Technology helps make healthcare more efficient and affordable



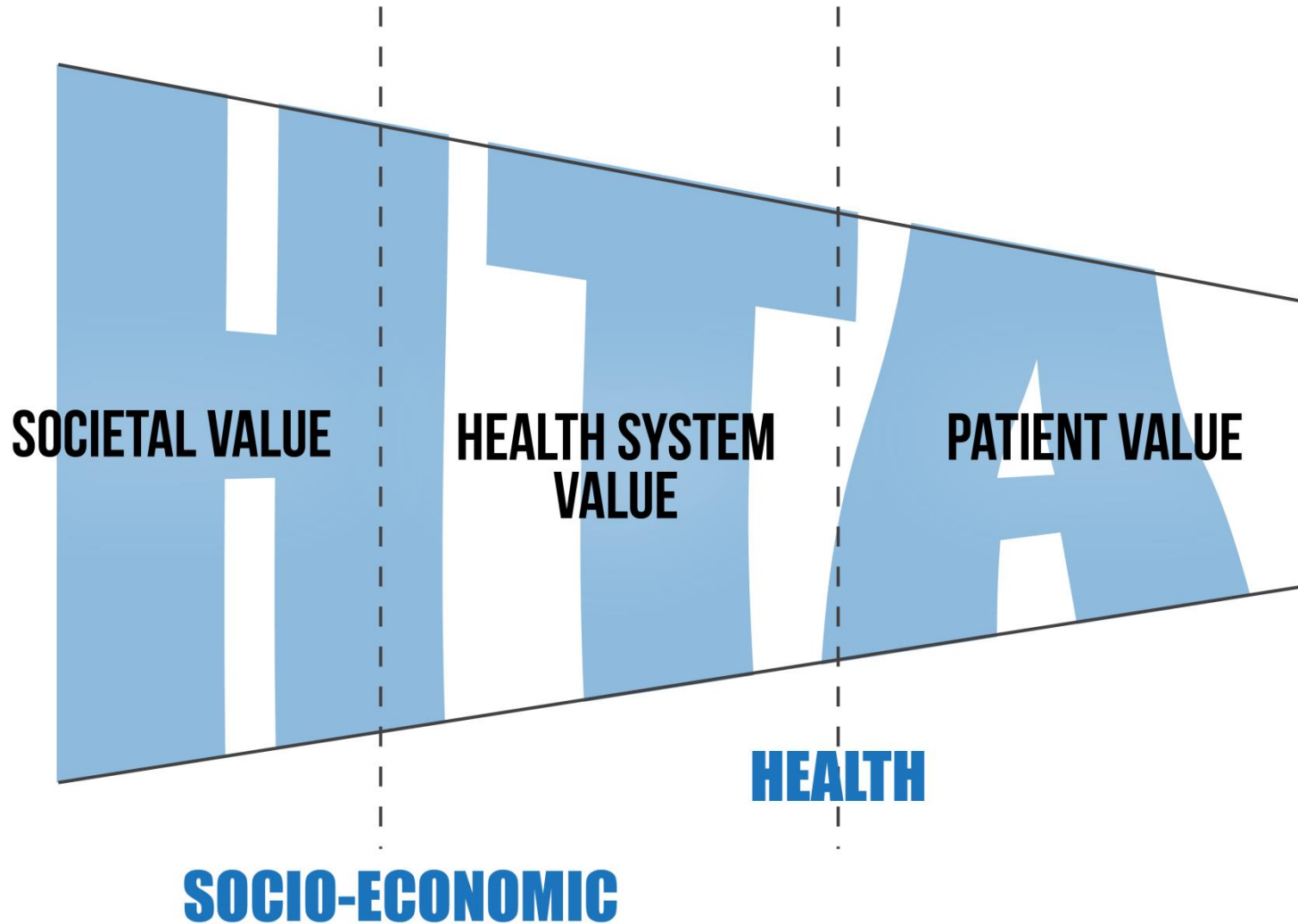
Medical Technology Unique & Different Market Access Model in Europe



- Learning curve
- Continuous innovation to improve outcomes
- Competitive market dynamics
- Limited data and patent protection



Potential interest in concept of HTA



HTA for IVDs in the context of market access [Link](#)
Eucomed HTA Position Paper [Link](#)

Has HTA been useful for Medical Devices & IVDs in Europe?



NO SPECIFIC METHODS FOR VALUE DEMONSTRATION



MD & IVD Industry is reluctant to further engage

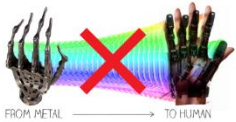
MULTI DEMANDS



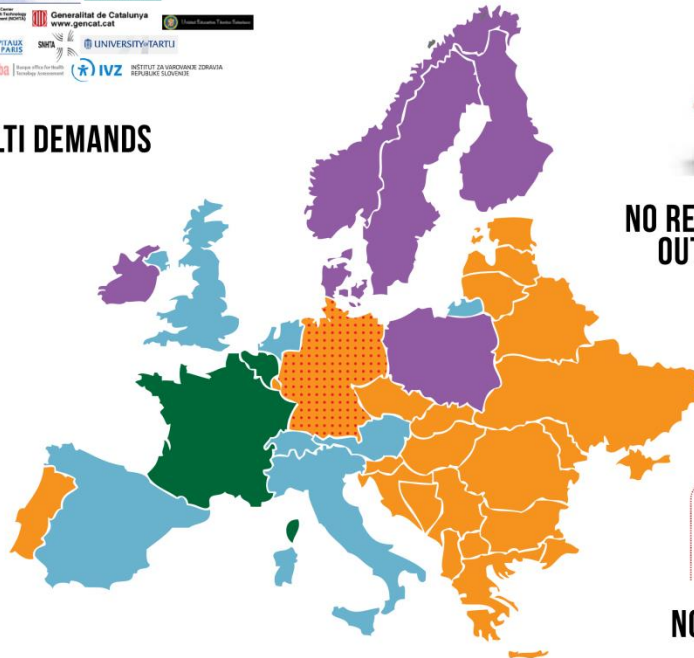
NO RECOGNITION OF SPECIFIC OUTCOMES AND VALUES



**HTA-N
European
Cooperation
of value?**

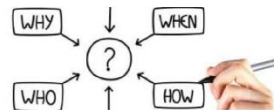


DELAY ACCESS TO INNOVATION



NOT FIT-FOR-PURPOSE

NO SPECIFIC EXPERTISE



EU HTA Collaboration Could Be of a Value if HTA Network...

1. Acknowledges that European access model is unique to bring the value of innovation to patients in Europe;
2. Acknowledges that CE-mark demonstrates safety and performance;
3. Ensures that HTA doesn't jeopardise innovation, SMEs and doesn't delay access;
4. Shifts focus from cost to value addressing unmet needs, through specific and appropriate methodologies;
5. Ensures that HTA is fit-for-purpose = informs decision making



HTA Network Recognizes That



- **Trust** is a precondition for a *successful cooperation ... through expertise, development of capacities, and high quality output.*
- Cooperation is based on **good governance**, including: ...appropriate *stakeholder involvement.*
- Cooperation should respond to the *needs of different target audiences ... payers, developers of health technologies* and provide support for decision-making in health care.



HTA Network goals for Medical Devices and IVD



- HTA can be instrumental in promoting innovation that delivers better outcomes for patients and society as a whole
- It provides evidence-based information and analysis useful
 - in making decisions on how to allocate resources
 - achieve sustainable healthcare systems
- Increase use, quality and efficiency of HTA... in decision-making, in accordance with national practices and legislative frameworks
- Cooperate more efficiently in defining evidence requirement through the life cycle of technologies from scientific advice to surveillance after introduction to healthcare practice
- Synergies between HTA and regulatory issues
- EMA hosting the Network



Priorities

**WHERE EU HTA COOPERATION
COULD BRING VALUE?**



We Call for Teaming Up For Value and Investment



Establish an HTA Network Level Medical Devices & IVDs Platform to define the value, governance, modalities and activities of the HTA cooperation in Europe



We Call for Building Operational Expertise and Quality Assurance Mechanisms



Focus on **building HTA expertise**, most appropriate methodologies for medical devices and IVDs, certification and quality assurance mechanisms





COCIR Profile and expectations and limits



Industry sectors covered by COCIR



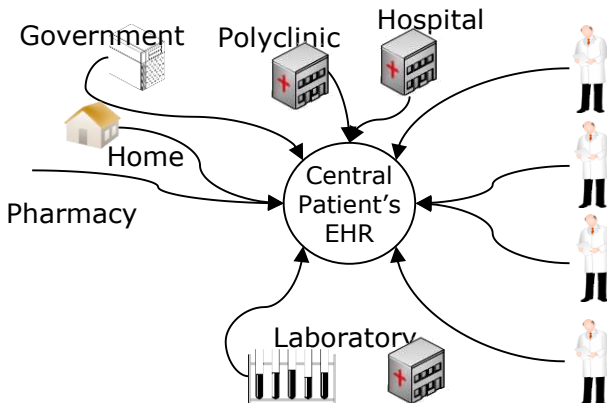
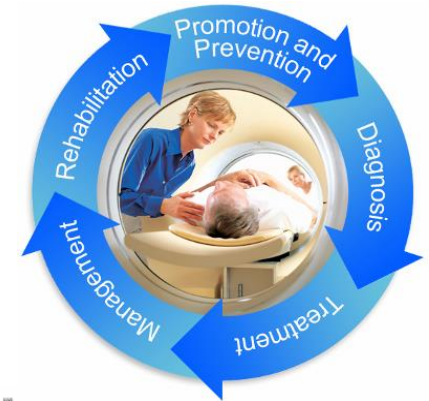
COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe



COCIR covers 4 key industry sectors:

- Medical Imaging
- Radiotherapy
- Electromedical
- Health ICT

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





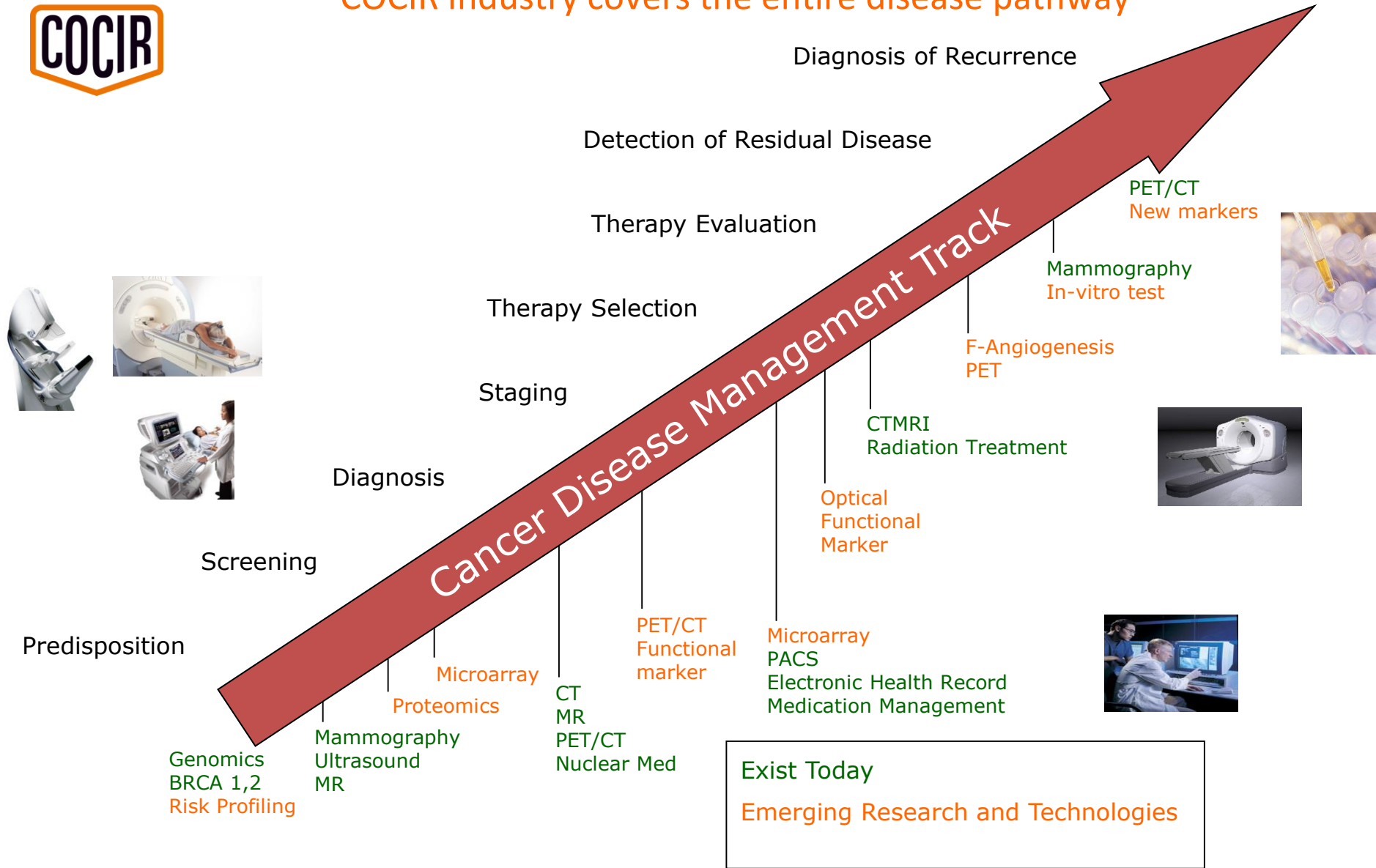
32 Member Companies



14 Member National Trade Associations



An example: COCIR Industry covers the entire disease pathway





COCIR considerations on HTA

1. COCIR agrees & supports *more* cooperation on HTA:
 - To expedite the transfer of effective & cost-effective 'medical technologies'
 - To avoid duplication of effort and increase efficiency
 - To reduce uncertainties
2. The value of 'medical technologies' to healthcare providers, needs to be evaluated *differently* from pharmaceuticals & other medical devices – Need for a broader perspective
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



Need for a broader perspective

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

- **Clinical** → patient outcomes
- **Organizational:**
 - Increasing throughput
 - Reducing downtime
 - Etc
- **Societal:** reduced absenteeism from work/increased productivity at work → improving the economy



- Saving scarce resources
- Improving efficiency of healthcare

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

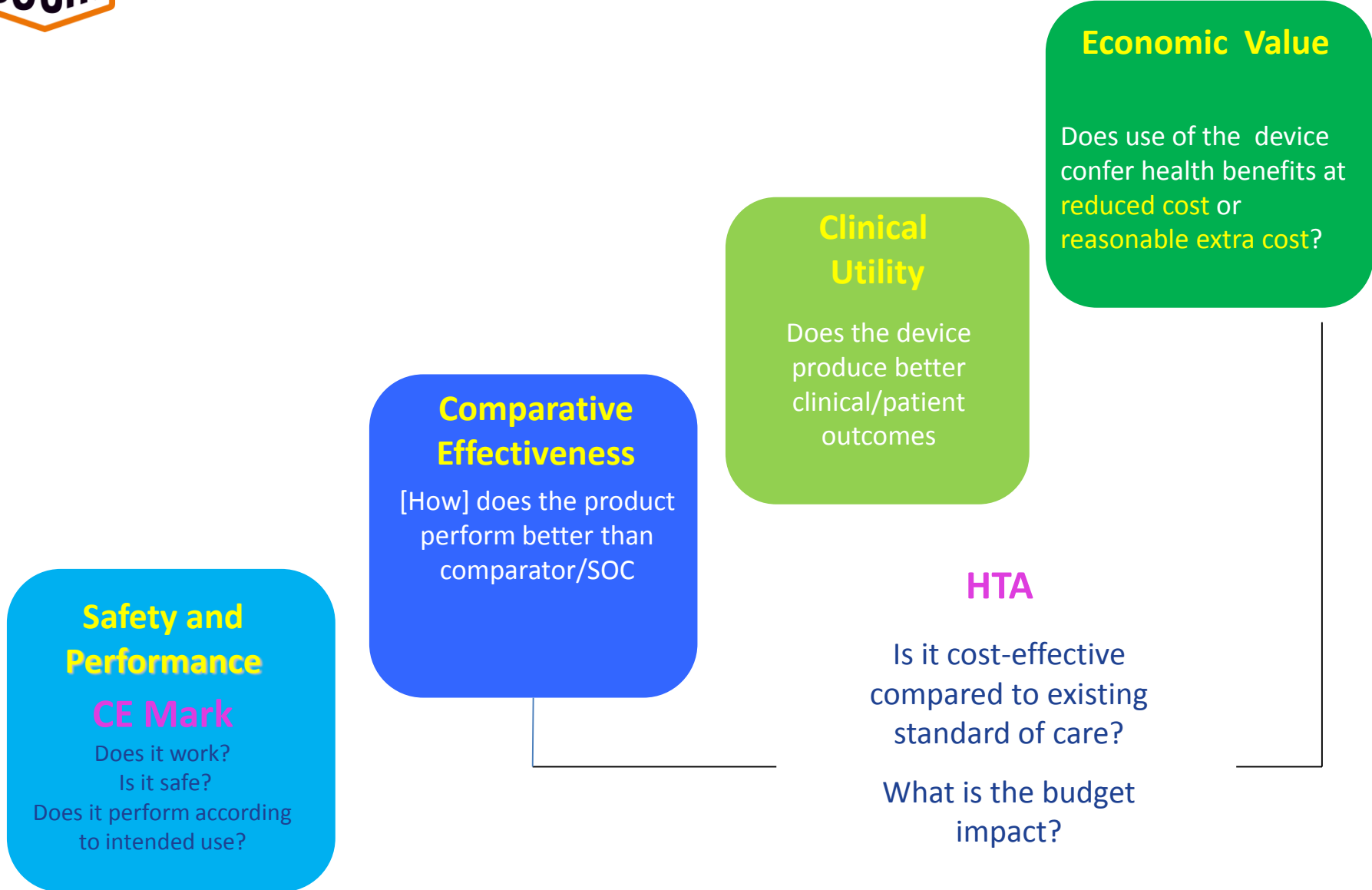


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Importance of IT support



Differentiation between CE Mark and HTA





COCIR call for HTA Network

1. Need trust in Industry: Industry is part of the solution and not part of the problem. One Observer seat: number and status is not enough.
2. Don't mix CE Mark and HTA!
3. Need effective coordination between Member States to increase efficiency and limit complexity and cost burden
4. Need coordination between various initiatives (e.g. AdHopHTA)