THE EVOLVING EU POLICY LANDSCAPE

ARE WE ON THE RIGHT PATH TO IMPROVE CLINICAL AND ECONOMIC OUTCOMES RESEARCH OF MEDICAL DEVICES?

Carlo Federici
Carlo.federici@unibocconi.it

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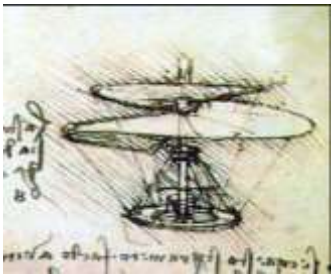
Gap between regulatory and HTA-relevant evidence



Challenges in the assessment of Medical Devices

Centralized assessments for MDs: trojan horse or blessing in disguise?

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Regulations open to early dialogues and Regulatory/HTA allignements

- MDR – Art. 57 on early SA
- Scrutiny procedure and link with JAs

Time for more efficient evidence generation processes?

- Timely, fit for purpose development plans?
- Relevant for all stakeholders (multi HTA, regulatory/HTA)

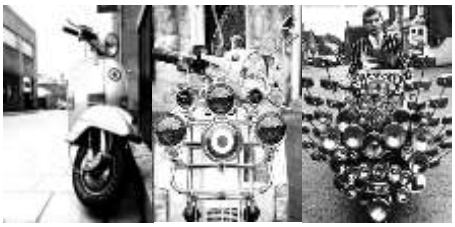
Yes, but…

What Evidence is approriate?

Need to balance benefit of adoption VS benefit of further evidence

Safety, efficacy, comparative effectiveness, economic performance, HRQoL

MD-related: learning curve, broader organizational impact including training and infrastructure



Product iterations

Fast-followers products

How much early?

- Start early and take the risk of poorly relevant evidence (due to technological changes) or wait until more definitive designs are achieved and loose relevant data?

What study design?

- RCTs always optimal choice?
- May require flexible designs to incorporate technological iterations and new comparators**.**

EDs may discuss optimal timing and study design that fits all requirements

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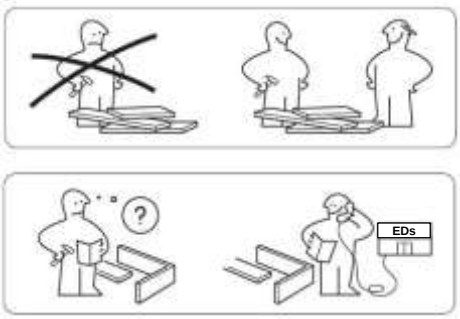

Residual uncertainties on clinical and economic performance remain after clinical evaluation

What is the minimum viable evidence to grant access and reimbursement?

- EDs as the ideal time to agree on what need to be demonstrated in clinical evaluations and what will be monitored via post launch evidence generation processes

Share the risk?

- EDs could inform future discussion on conditional reimbursement schemes to share the risk between manufacturers and payers.
- Generic and MD-specific challenges in design

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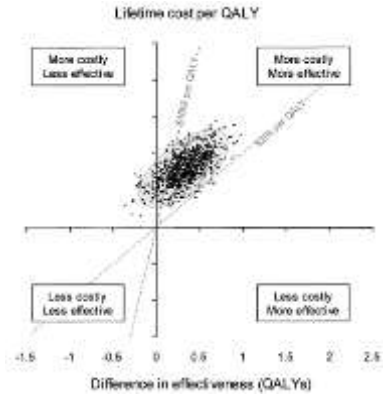

Economic evaluations relevant to grant reimbursement

What role for (early) economic evaluations?

- Consistent, explicit framework
- Support discussion during early dialogues about payers' evidence requirements pre and post-launch.
- Can be used for and with JAs
- Inform post-launch evidence generation

Adopt a life-cycle perspective

- Update whenever new evidence becomes available

Challenges

- Modelling without solid clinical evidence
- Require agreement on alternative sources of evidence (In silico trials, computer modelling and simulation, expert opinions), as well as quality and reporting standards

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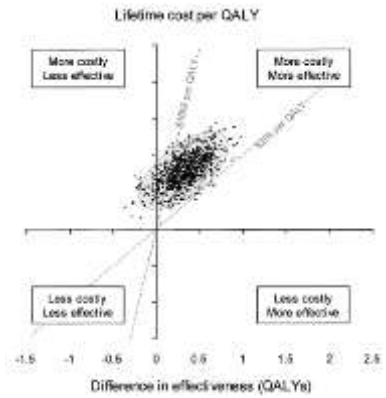

Economic evaluations relevant to grant reimbursement

Collect evidence relevant to economic evaluation early on during Clinical development processes

At an early stage, more emphasis on informing research prioritization, optimal study design, and characterization of the uncertainty, rather than economic performance

- Require agreed standards on how to report and communicate early economic models

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- Great opportunity to better aligned, more efficient evidence generation processes
- EDs has potential to get an agreement on evidence generation plans including post-launch follow up
  - Parallel Regulatory/HTA EDs challenging for MDs but things may change in the future
  - Still require agreement on methods and procedures
- Don't leave economic evaluations behind!
  - (Early) economic evaluations may contribute to avoid unneccessary delays in market access of MDs
  - Consistent, explicit framework supporting discussion on HTA-relevant evidence requirements along products life-cycle
  - Need quality and reporting standard and agreement on evidence sources

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THANKS.

CARLO.FEDERICI@UNIBOCCONI.IT

Università Bocconi
CERGAS
Centre for Research on Health and Social Care Management

Via Bocconi 8| 20136 Milano – Italia |
Tel +39 02 5836.2596/2597/5266

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