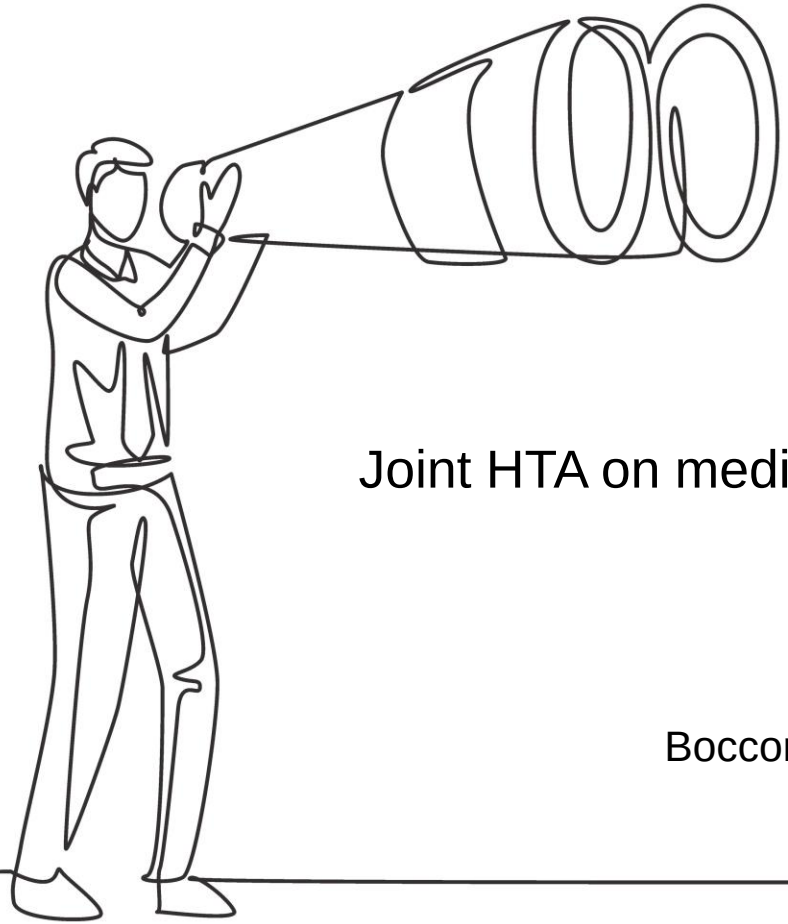
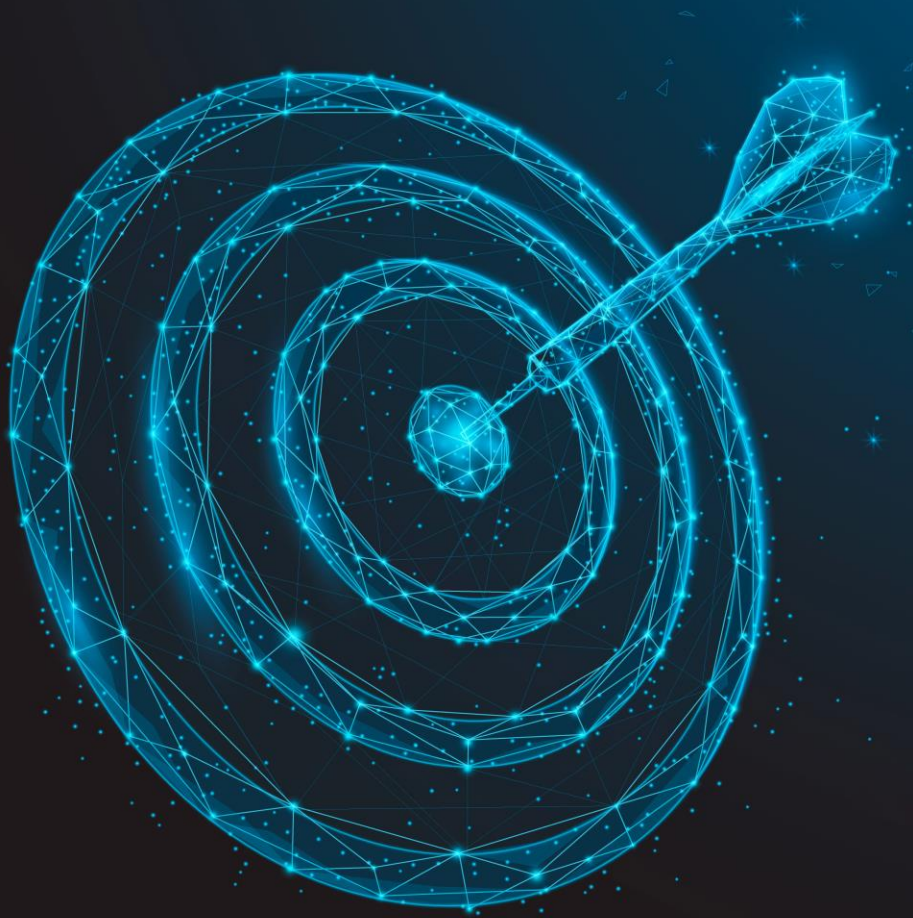


Joint HTA on medical devices – Looking ahead

Rosanna Tarricone, PhD
Associate Dean
Bocconi University School of Management

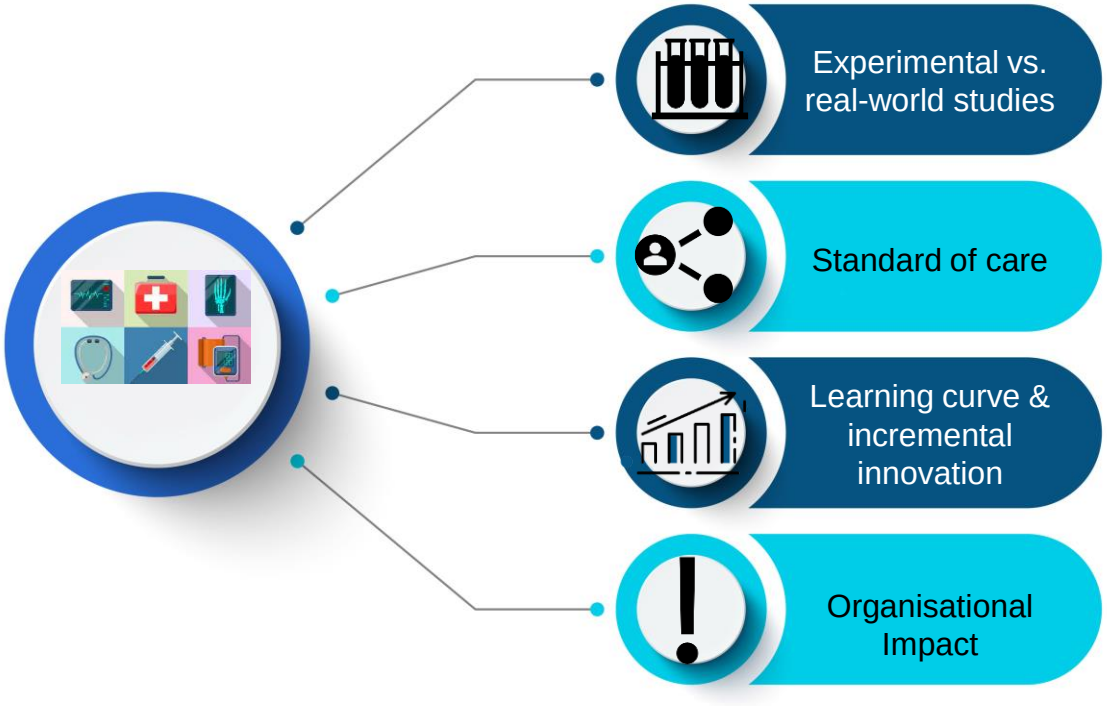


Joint Clinical Assessments (JCA)’s advantages:

- To generate «fit-for-purpose» clinical evidence only once
- To rely on harmonised assessment methods
- To rely on transparent procedures (e.g. relations with stakeholders)

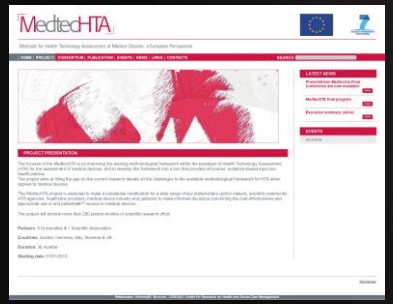
GOAL

Key challenges in evidence generation for Medical Devices



Università Bocconi
MILANO

The European Commission has hugely invested to advance methods for the assessment of MDs



Università Bocconi MILANO

Is there any other challenge?

Implications of the HTAR can not be disjointed from the MDR's:

- The requirements for clinical evidence in the MDR may increase the time to market approval.
- The requirement for JCAs for high-risk devices will be centralized; however, each single Member State may want to complement with additional data which may lengthen the assessment process.
- Since coverage and reimbursement decisions will remain decentralized, this could further delay patient access in some Member States, particularly if the clinical evidence generated in the earlier stages of the approval process is not sufficient for the assessments made by HTA bodies.

It is critical that appropriate evidence on the clinical effectiveness of high-risk devices is delivered in a timely manner and that the links between regulatory approval and coverage are considered

Time for an EU Early Dialogue?

The MDR Expert Panels can liaise with the Joint Scientific Consultation Experts and work with the industry to identify the conditions to develop fit-for-purpose clinical evidence

Time for an EU Accelerated Access Program?

An EU “Accelerated Access Pathway” for high-risk MDs can be developed in response to lengthier patient access process and to similar programs in other jurisdictions (e.g., Breakthrough Device Program in US, Accelerated Approval in Australia,..)

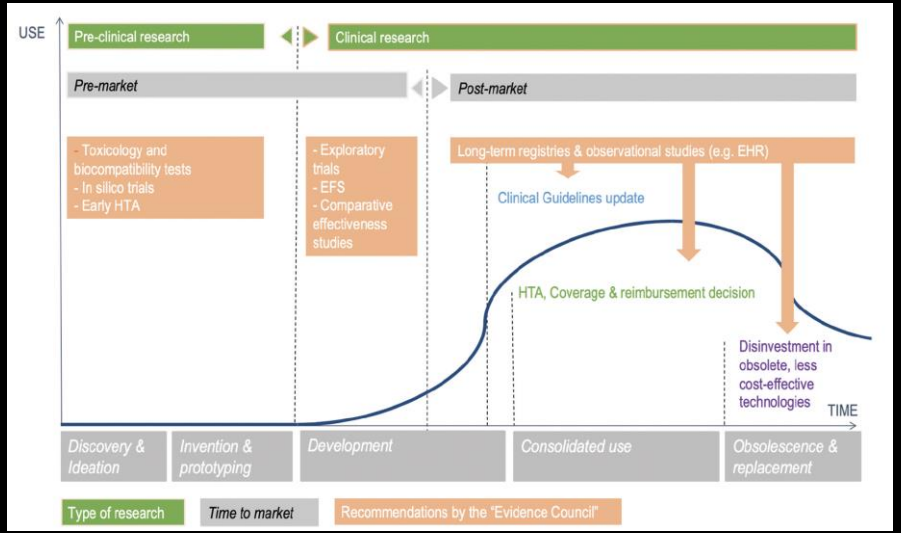
Time has come to make the difference

- The distinctive features of MDs need to be finally considered in the development of assessment guidelines
- Methodological advancements and policy recommendations emerged by several EU-funded projects need to be further leveraged when assessment frameworks are developed
- All stakeholders' expectations need to be actually considered (e.g., patients' PROMS when health outcomes measurement is at stake)
- The conventional linear "pre-market"→"post-market" attitude must be replaced by a circular lifecycle approach

To anticipate the “business case” with a lifecycle approach

- Effective lifecycle planning requires a roadmap of what evidence will be needed at each stage of the product development

- The early pre-market stages will be not only for planning safety and performance-driven studies but also for **<u>making the business case</u>**:
  - where the device sits in the diagnostic and therapeutic landscape and what advantages it offers vs SoC
  - and for anticipating the evidence needs to support this case in light of regulatory and HTA considerations



Tarricone et al. Lifecycle evidence requirements for high risk implantable medical devices: a European perspective. Ex Review of Medical Devices 2020; https://doi.org/10.1080/17434440.2020.1825074

To anticipate the “business case” with a lifecycle approach

- Early Feasibility Studies
- Early HTA
- Early Dialogue

Upskilling exercise for all relevant players

The HTAR for Medical Devices needs some time to be implemented but, do not forget that….

it’s always too early until it is suddenly too late (Martin Buxton)

Bocconi

THANK YOU.

rosanna.tarricone@unibocconi.it

Università Bocconi
MILANO