# THE EVOLVING EU POLICY LANDSCAPES: ARE WE ON THE RIGHT PATH TO IMPROVE CLINICAL AND ECONOMIC OUTCOMES RESEARCH OF MEDICAL DEVICES?

***An R&D manufacturer perspective***

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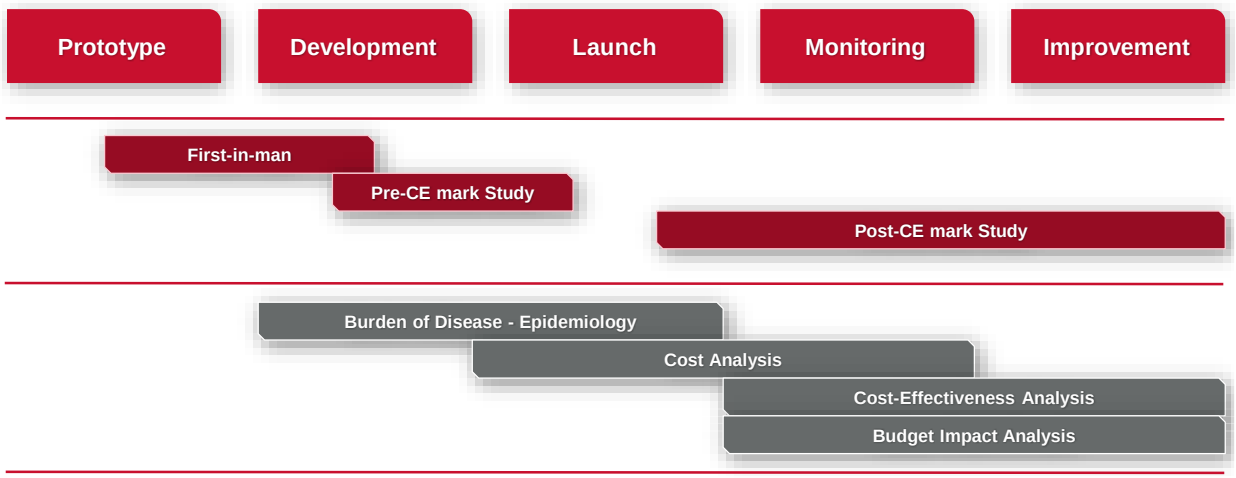
## The current framework of evidence generation



# Pragmatic pathway to evidence generation I

**CLINICAL**
- first in human → early evidence → pre-CE Mark matched-cohorts → post-CE → registries

**ECONOMIC**
- burden of disease → cost-analysis → cost-effectiveness → budget impact → affordability

**FUNDING**
- innovative payment schemes → case-mix systems/add-on payments → established funding

**Data drive policies - Policies drive investment and funding decision**



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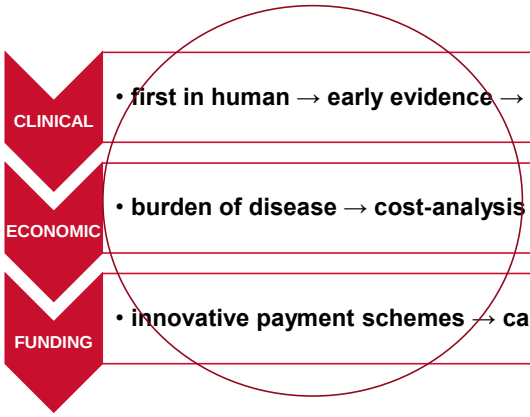

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# Pragmatic pathway to evidence generation II

- **Accelerate patients access to best-in-class innovative life-saving technologies**
- **Timely adoption of complex-implantable innovative medical technologies – Class III MDs**

1. **Framing a trusted early dialogue process** between technology developers, regulators, HTA assessors and funding authorities, including clinicians on patient-centered health outcomes
2. **Prospectively** agree on methodologies sufficient to address three major uncertainties: **clinical learning curve, patients performances learning curve, manufacturers learning curve**
3. **Setting an efficient integrated approach** to facilitate evidence generation by effective planning for early funding and coverage of new technologies to maximize patient access





# Pragmatic pathway to evidence generation Early Feasibility Studies framework

**Linking early dialogue to early evidence generation**

- Early feasibility Study – Medical Device Innovation Consortium (MDIC)
- PPP – to provide proof of principle and initial clinical feasibility and safety data collection
- Small number of patients (usually ≤15) and limited number of investigational sites

**Maximise early learning curve, limit variability in early assessment, gain early understanding of potential patients benefits**

# Value of pragmatic evidence generation framework

- ✓ **Early agreement** of target disease / unmet medical need/ patient population
- ✓ **Early estimation** of potential patient benefit and patient preferences
- ✓ **Early understanding** of the impact on patient pathway and organization of healthcare
- ✓ **Early financial planning** to progressively adopt innovative technologies
- ✓ **Early data collection** to be projected in the pre- and post- CE mark to inform HTA and payers

**Link horizon scanning to early dialogue**
**Link EFSs to HTA**
**Link early funding to coverage with evidence development**



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***Monday, November 12, 2018***

**THE EVOLVING EU POLICY LANDSCAPE: ARE WE ON THE RIGHT PATH TO IMPROVE CLINICAL AND ECONOMIC OUTCOMES RESEARCH OF MEDICAL DEVICES?**

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