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

Prototype | Development | Launch | Monitoring | Improvement
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First-in-man | Pre-CE mark Study | Post-CE mark Study

Burden of Disease - Epidemiology
Cost Analysis
Cost-Effectiveness Analysis
Budget Impact Analysis
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
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
Monday, November 12, 2018

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