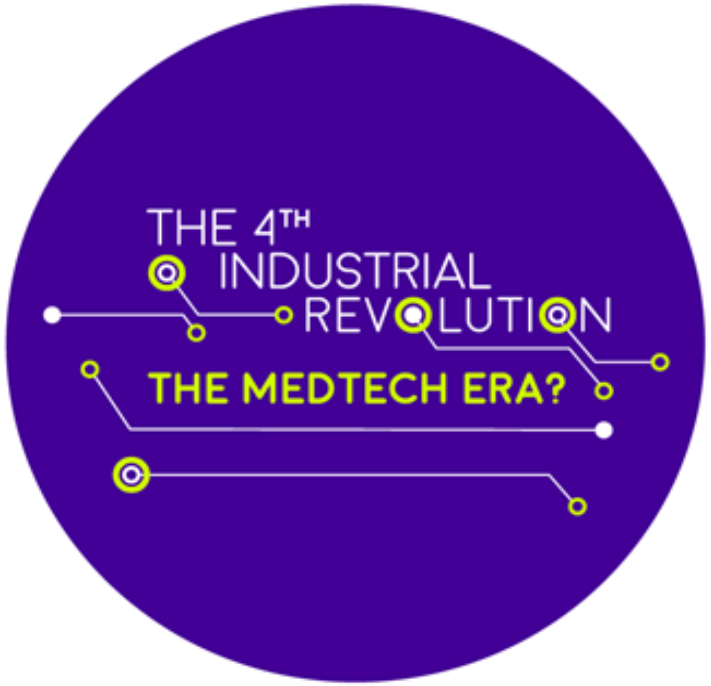
Evaluation Bodies, Payers, and Hospitals

Aligning Expectations



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We live in challenging times

- In most developed nations the share of GDP devoted to healthcare continues to grow
- We face competing budget demands within EU deficit targets
  - Within healthcare
  - Health vs non-health priorities (e.g., infrastructure)
- As population mean age increases over the next 20-25 years the problem is likely to get worse, not better
- Most countries have introduced some form of prospective payment for hospital services
  - In most cases this means no separate payment for MedTech
- And at the same time, technology continues to advance rapidly
  - Sometimes the advances are incremental, sometimes quantum (e.g., 3D printing)

How do we manage it all in MedTech?

- The key protagonists in MedTech:
  - Hospitals
  - Payers
  - HTA bodies
- Historically there was no need for HTA bodies – coverage/reimbursement followed marketing authorization, and decision making was based mainly on clinical efficacy
- HTA bodies were created (and legally empowered in some countries) to be a (quasi) independent judge
  - In some instances, of clinical evidence only
  - But in many others, of “evidence of value” also

What does this mean for MedTech?

- Showing clinical benefit alone is no longer enough
  - *Comparative value* vs. “best available treatment” is the new standard
    - …and that treatment isn’t necessarily a “predicate technology” – it could be a drug or some other intervention
  - Does the new technology offer *reasonable value for money*?
- The burden of proof for “value for money” is on MedTech
  - In most cases the audience will be the hospital, not the payer, because there is no add-on reimbursement
  - HTA bodies have less sway in these cases as there is no incremental funding at stake
- In cases where add-on reimbursement is available, HTA bodies play a much more important role (much as with pharmaceuticals)

What can MedTech expect in the future?

- To face increasing evidence hurdles
- To incur the cost of developing "evidence of value" where it does not currently exist
    - …and that includes evidence from real-world use post-marketing authorization