Methodological Guidance for the Life Sciences Industry.
An Industry Perspective

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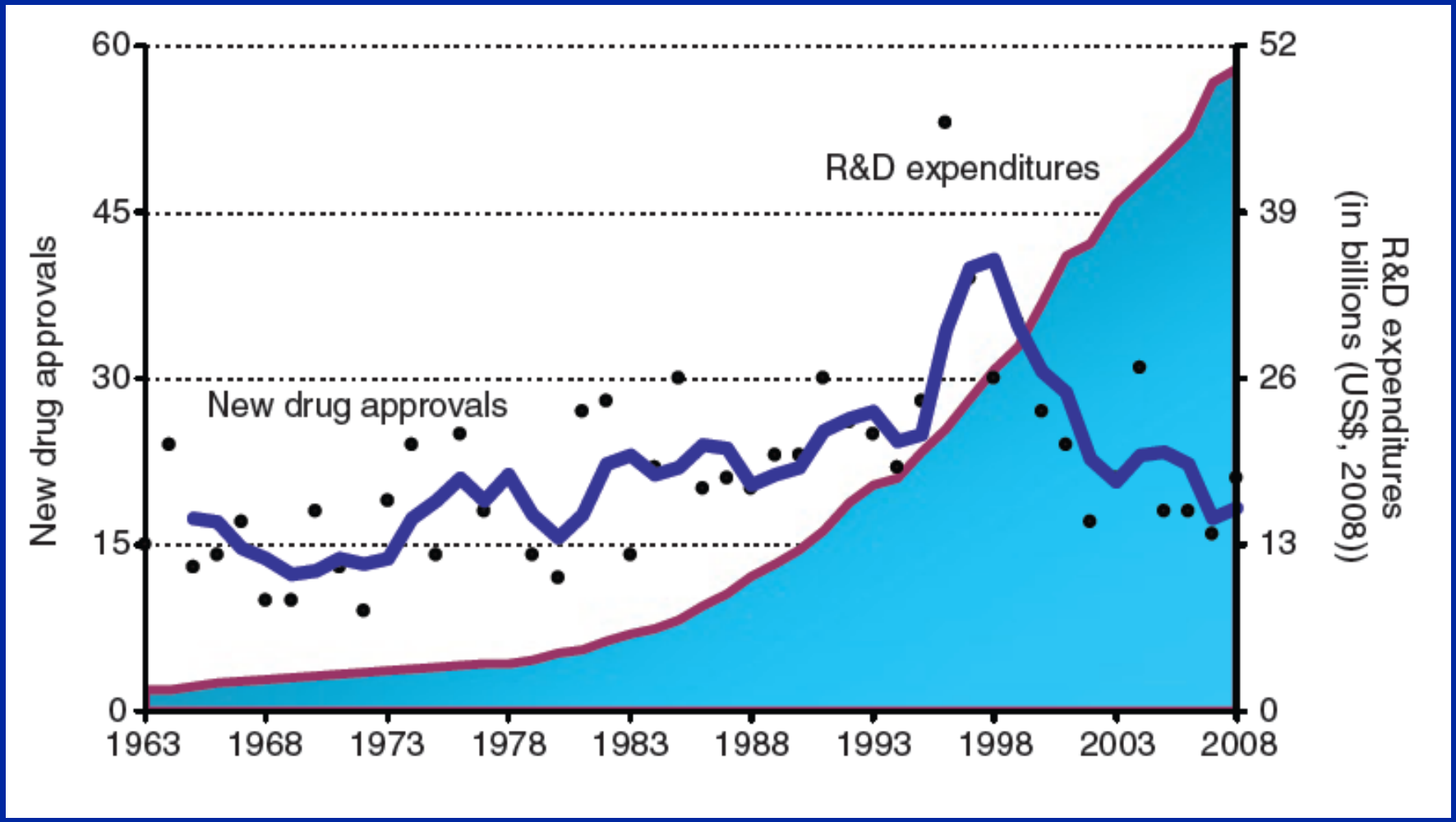
What is the issue?

Technology development decisions

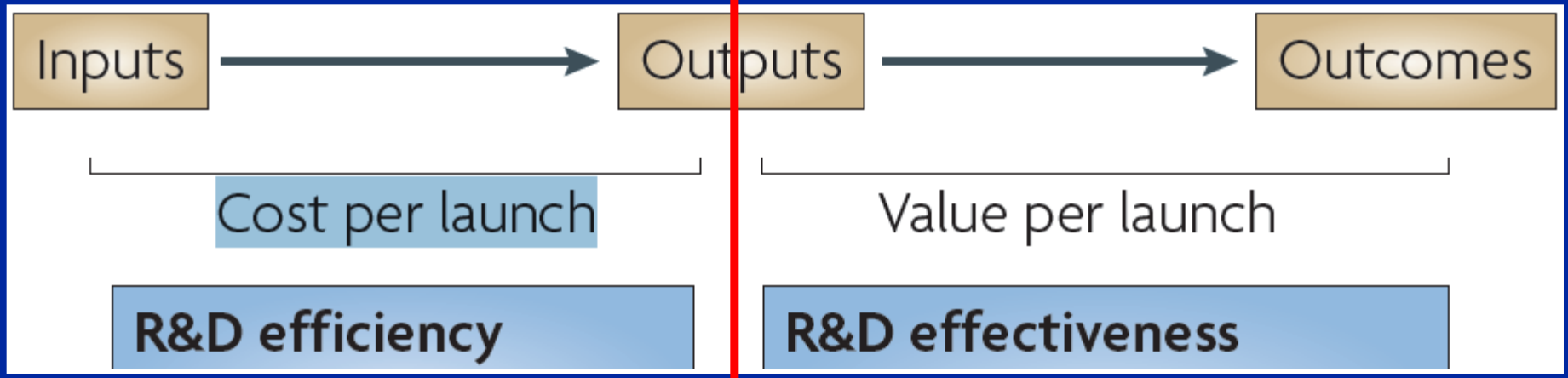
R&D investments increasingly challenged



Kaitin, Clin Pharmacol & Ther 2010

R&D efficiency and effectiveness

The two dimensions of R&D success



Adopted from Paul et al., Drug Disc 2010

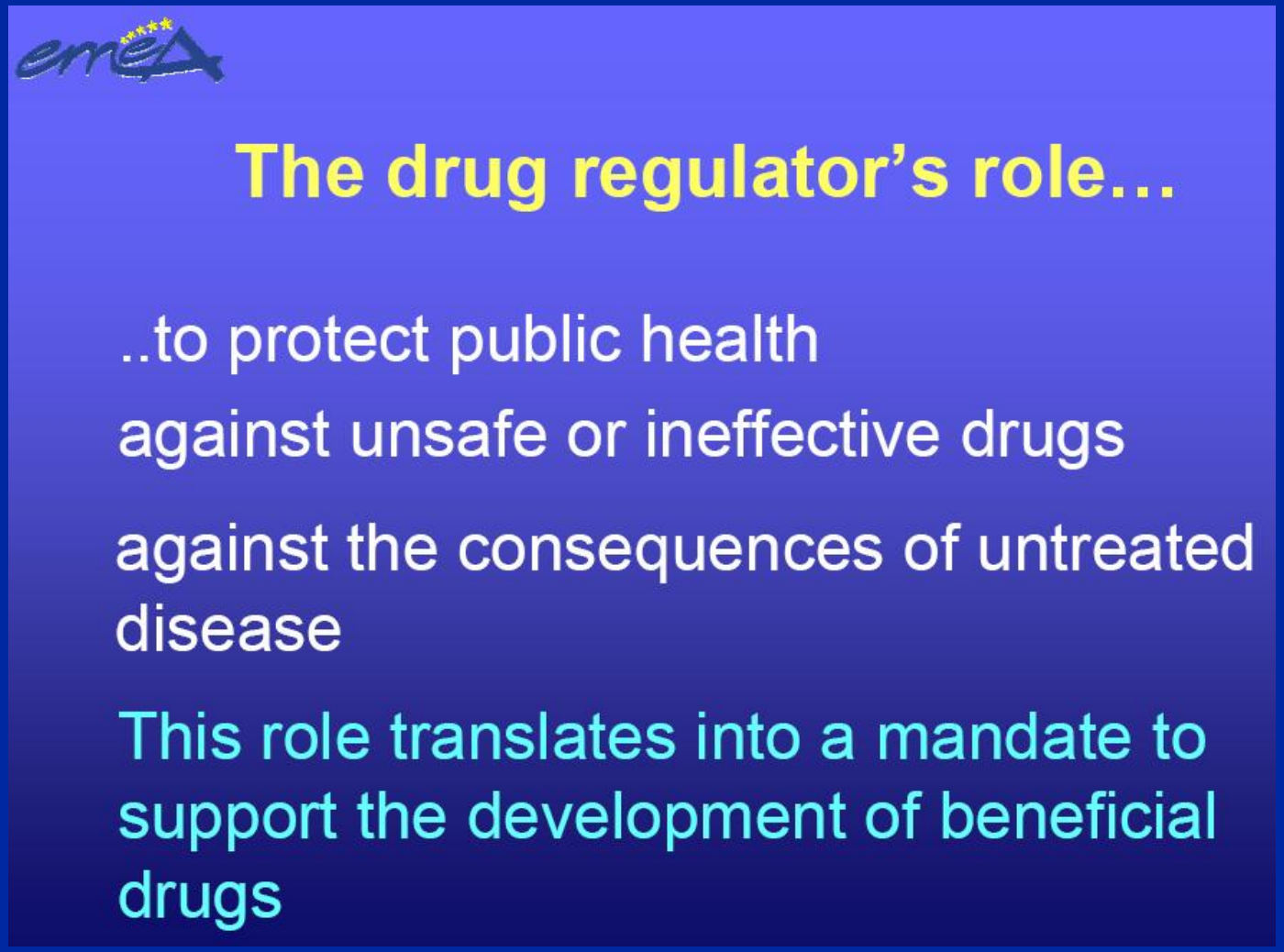
requires constructive and efficient interaction with regulatory authorities throughout development process

requires that patients and clinicians understand the value of a therapy as well as successful pricing, reimbursement, and funding negotiations

What can be done?

Regulators have started to position themselves

EMA and the "dynamic" aspect of its role



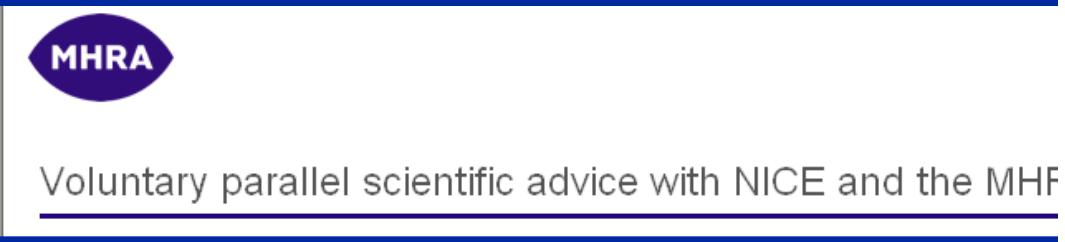
Hans-Georg Eichler, Edinburgh 2009

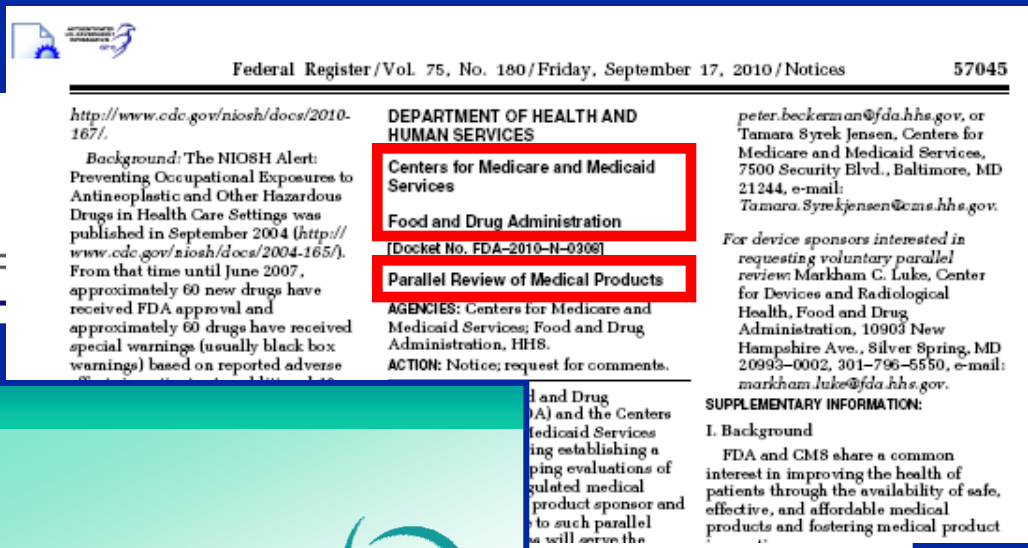
HTA agencies, payers and early advice

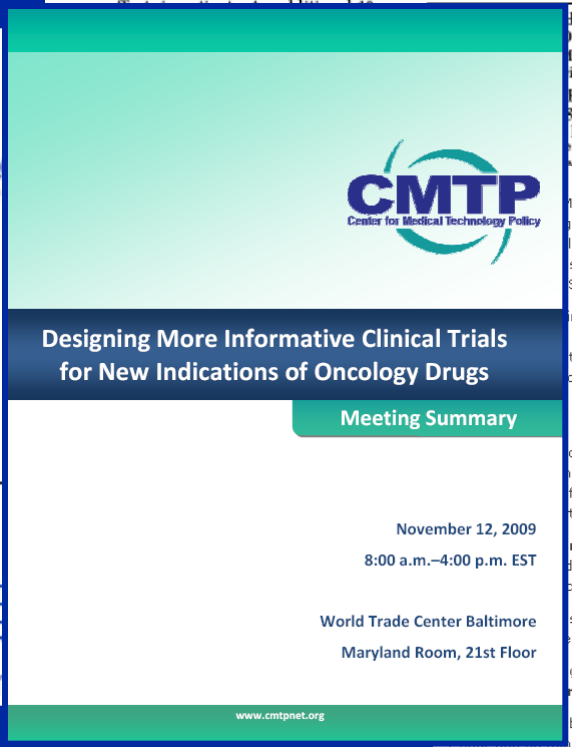
Isolated pilots or phase I of constructive engagement?

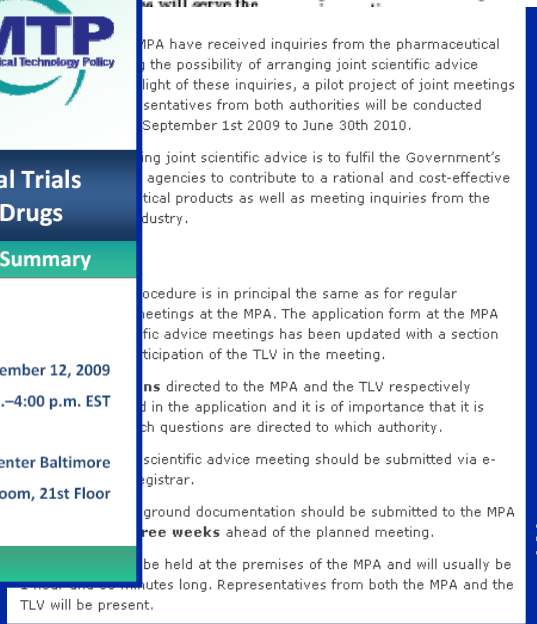
Multi-stakeholder consultations

Isolated pilots or phase I of constructive engagement?



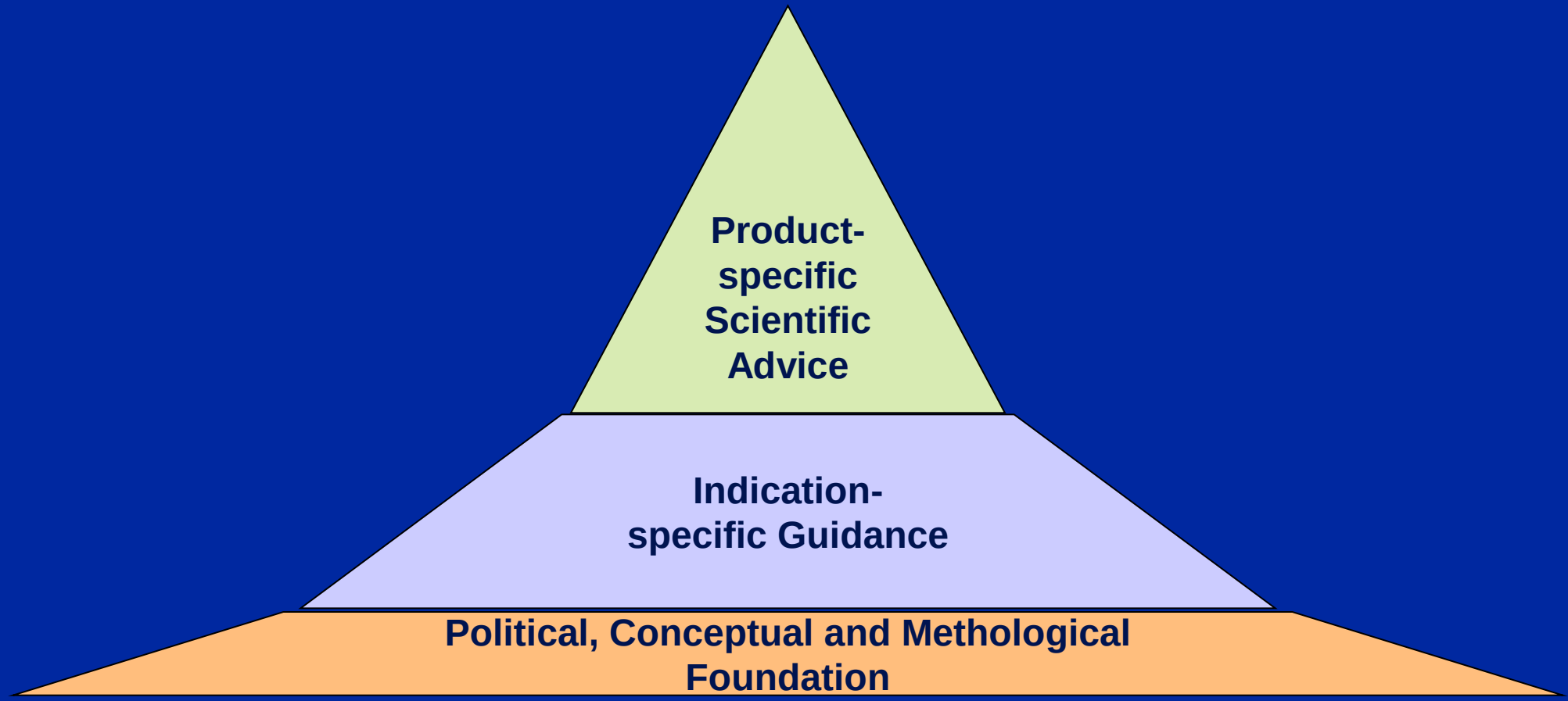






Good intentions exist - but action is needed

Subject layers of interest



“Reasonable” evidentiary and analytical standards
What does it need?

1. A shared interest of all stakeholders to establish “reasonable” standards i.e. to balance relevance, validity, feasibility, and timeliness
2. Sustainable platform(s) and resources to promote inclusive involvement of stakeholders (manufacturers, patients/providers/regulators and payers) and (other) experts
3. Transparency about the value of demanding additional evidence, the associated burden in terms of patient access delays as well as the longer term “dynamic” implications for the innovation process
4. Recognition of the global scope of technology development

But that’s easier said than done…

Participation, governance, processes and funding
Some first thoughts

1. ***Broadest inclusion of decision makers (technology developer, patients, provider, regulators, HTA agency, and payers)***
2. ***Build trust and understanding***
3. ***Recognize self-interest as the primary motive for constructive participation***
4. ***Recognize competition as the major source of better ideas***
5. ***Recognize opportunities to collaborate whenever these emerge***

We Innovate Healthcare

Participation, governance, processes and funding
Some first thoughts

1. ***Broadest of decision makers (technology developer, patients, provider, regulators, HTA agency, and payers)***

2. ***Build trust and understanding***
   - Participants need a clear understanding of each others roles and responsibilities, how they share interests and how they are different.

3. ***Recognize self-interest as the primary motive for constructive participation***
   - All participants will be inevitably „self-interested“, often labeled as „biased“. But there are more efficient ways to handle this than discrimination or exclusion.

4. ***Recognize competition as a major source of better ideas***
   - This endeavour does not need a monopolistic position that cannot be contested by those with even smarter ideas.