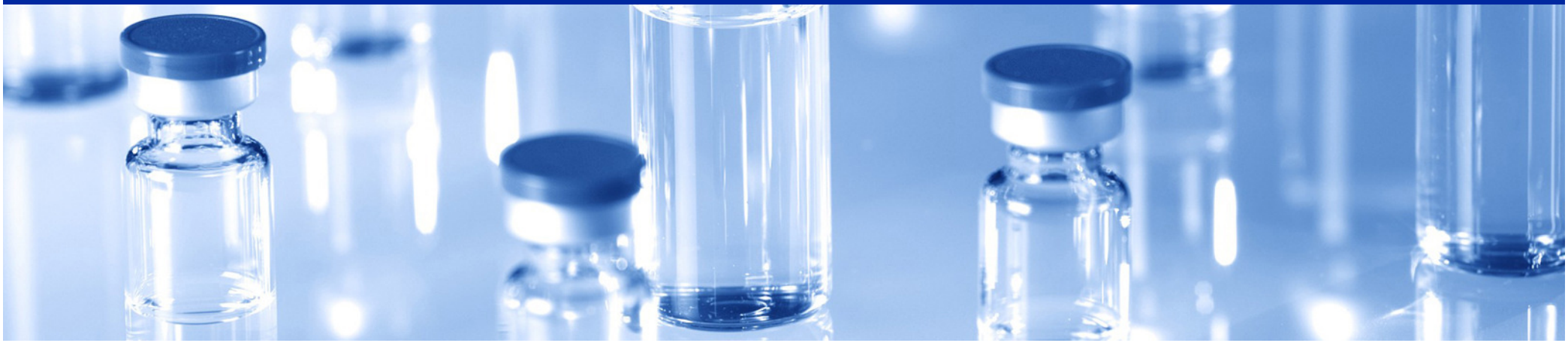
Innovation, regulation and increased payer demands

Ansgar Hebborn
Global Payer & HTA Program Policy, F. Hoffmann-La Roche AG, Basel, Switzerland

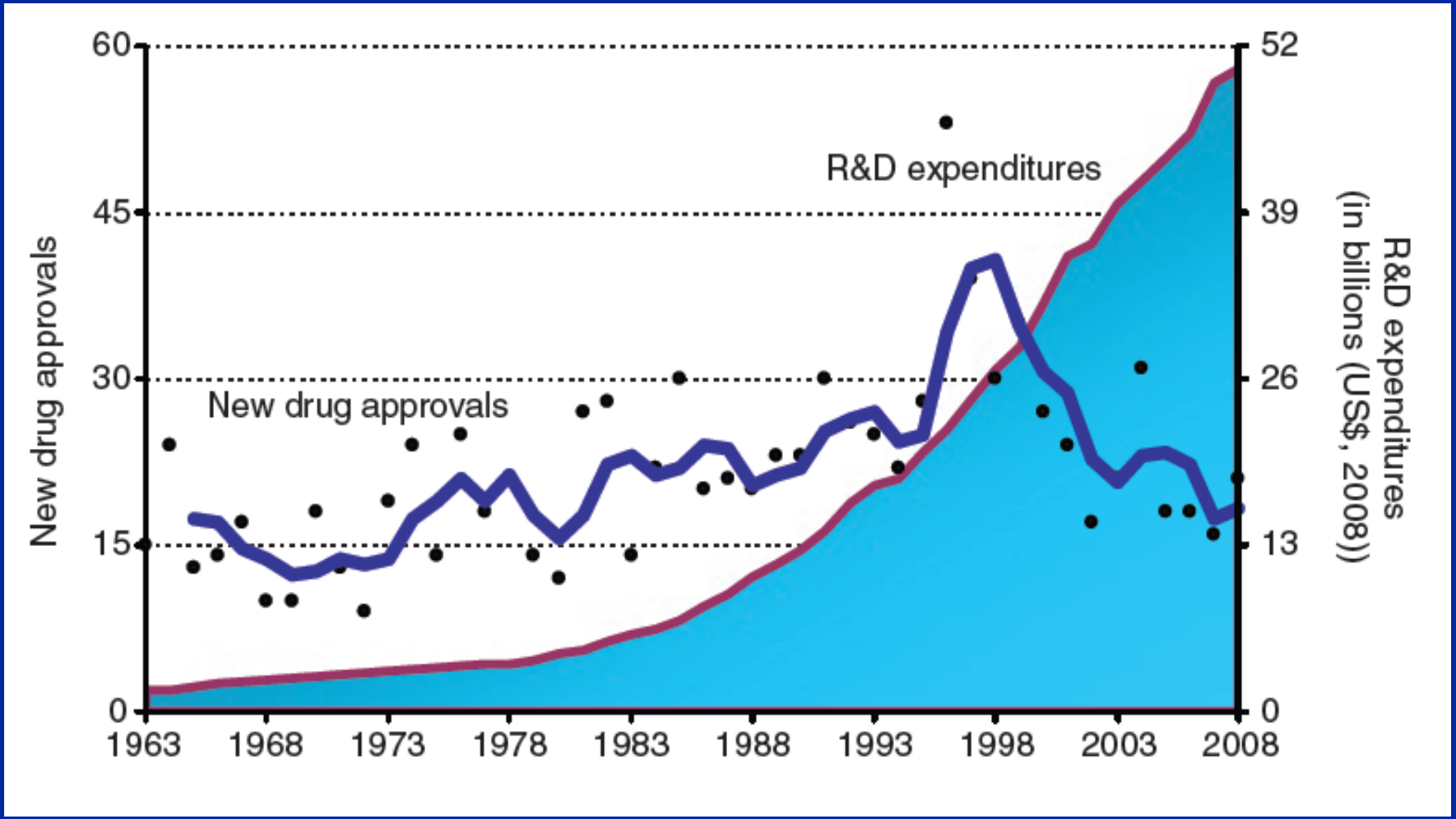
London, 18 February 2011



What is the issue?

Continuously declining R&D efficiency

R&D investments increasingly challenged



Kaitin, Clin Pharmacol & Ther 2010

Improving R&D efficiency

Strong voices in support of public/private partnerships

PERSPECTIVES

nature REVIEWS DRUG DISCOVERY

OPINION

Cutting the cost of drug development?

Michael D. Rawlins

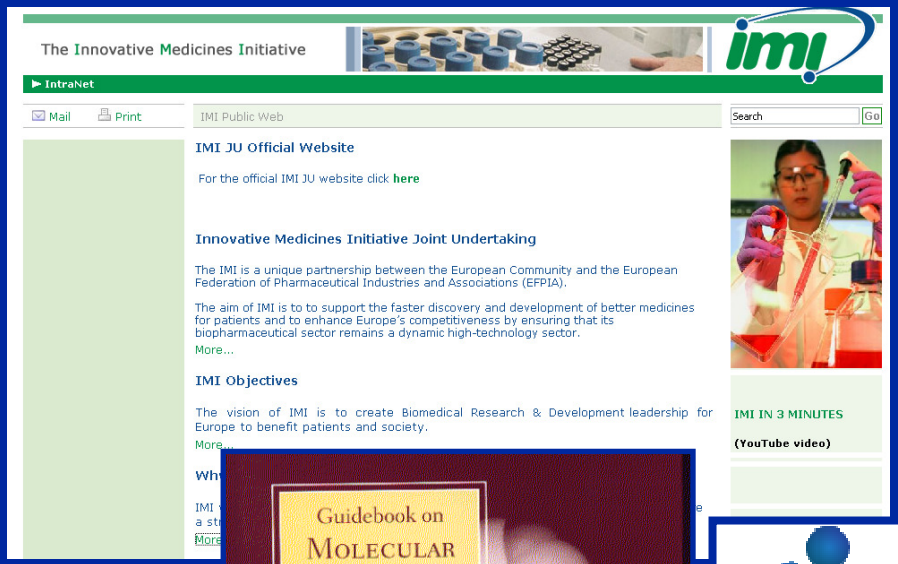
The cost of drug development has risen markedly in the past 30 years, with studies now reporting values exceeding US $800 million. As these spiralling costs threaten to make the development of new drugs increasingly unaffordable for both developing companies and consumers, it is clear that efforts should be made to address this problem. All aspects of the drug discovery and development process should be examined for potential cost savings, but I focus here in particular on the current regulatory requirements.

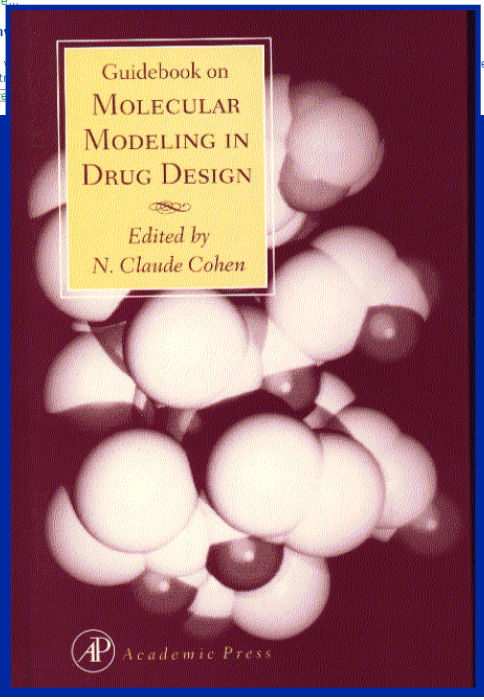
*"The time is now right for an exhaustive examination of the requirements of drug regulatory authorities. There needs to be a rigorous examination of the 'rituals' associated with drug development. Every step in the drug development pathway should be tested against two separate criteria: **is there a clear evidence-base to support the continuing inclusion of the measure in the requirements of regulatory authorities?**; and **does each regulatory requirement offer value for money?**"*

Rawlins, Drug Disc 2004

Initiatives, new tools and technologies

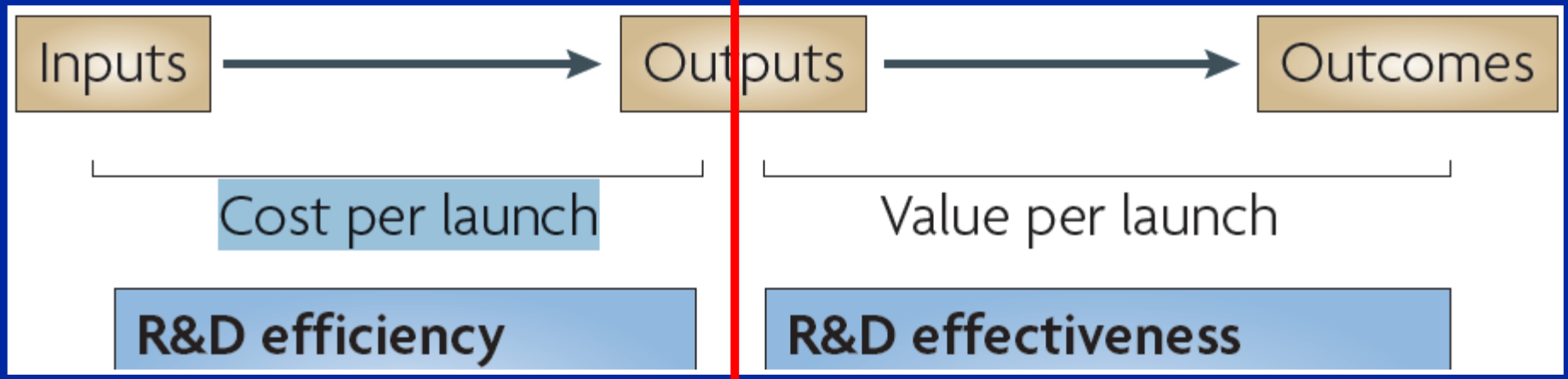
But how fast can they deliver?





R&D efficiency and effectiveness

The two dimensions of R&D success



Adopted from Paul et al., Drug Disc 2010

requires effective payer support (successful pricing, reimbursement, and funding negotiations)

Regulators have started to position themselves

EMA and the "dynamic" aspect of its role

The drug regulator's role…

..to protect public health

against unsafe or ineffective drugs

against the consequences of untreated disease

This role translates into a mandate to support the development of beneficial drugs

Hans-Georg Eichler, Edinburgh 2009

HTA and the diffusion of its gatekeeping role

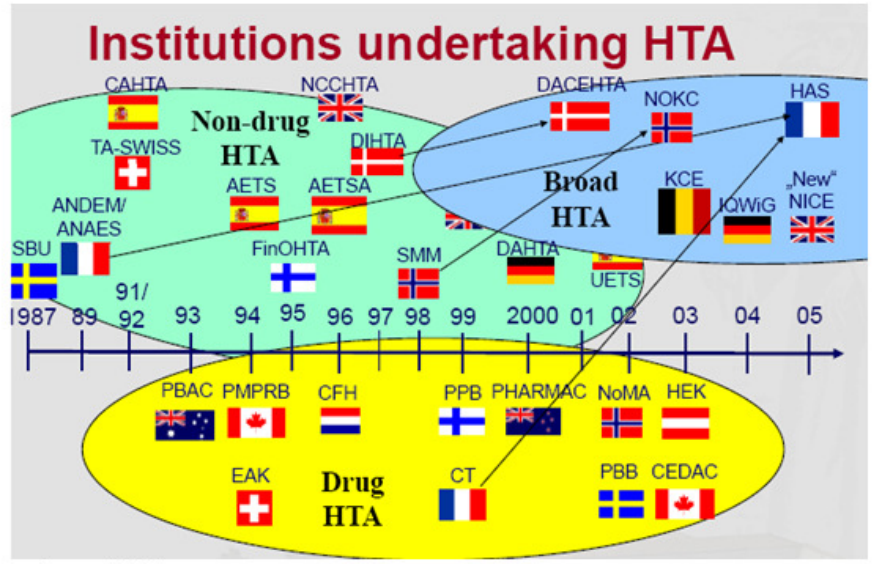
Not without impact on R&D effectiveness

EUnetHTA Partners

- 62* partners (59 original partners)
  - 34 Associated Partners (national/regional HTA agencies, MoH, research institutions, international organisations (Cochrane Collaboration)
  - 29* Collaborating Partners (e.g. WHO, OECD, CoE)
- 25 EU countries (÷ Slovaki
- 2 EEA (Norway, Iceland)
- Switzerland
- 4 institutions in countries o (Israel, Australia, Canada, U

- *as of January 2008 (4 organisa Collaborating Partners in 2007, www.eunethta.eu)*

EUnetHTA | European network for Health Technology Assessment |



Busse 2009

Regulatory authorities and HTA agencies

IQWiG and EMA - a"very different" remit?

An Agency of the European Union

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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The Agency provides the Member States and the institutions of the EU the best-possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to it in accordance with the provisions of EU legislation relating to medicinal products.

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IQWiG is an independent scientific institute that investigates the benefits and harms of medical interventions for patients. We regularly provide information about the potential advantages and disadvantages of different diagnostic and therapeutic interventions.

IQWiG's understanding of its responsibility

Peter Sawicki, Brussels, 17 April 2007

Roche

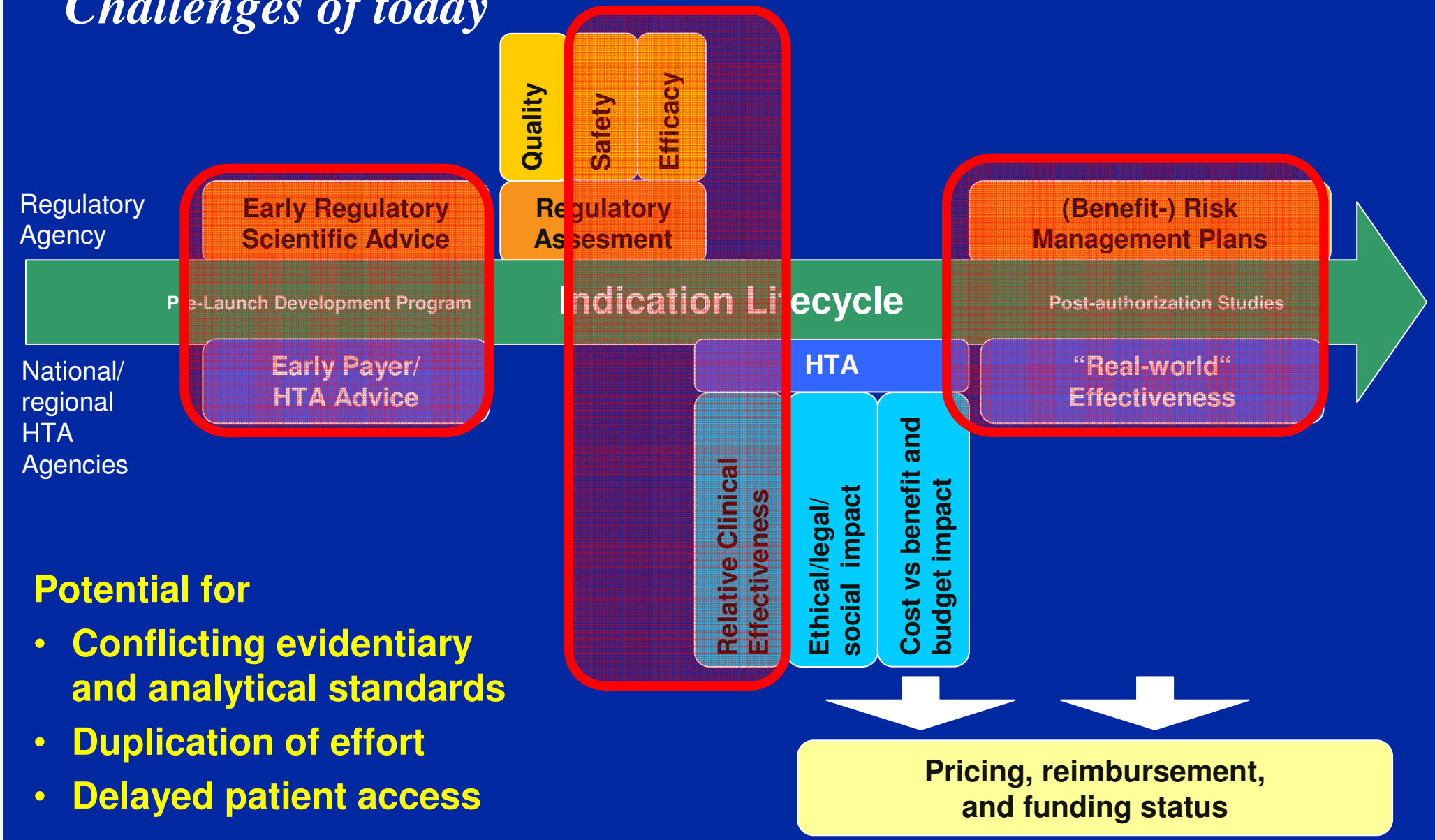
Evidence in the pharmaceutical policy

IQWiG resume after two years of work:

It is very difficult to protect the public and the individual patient from the threats to health and to the health-budget by the wide use of drugs with an unknown benefit - harm relation.

Regulatory-payer interface along the product lifecycle

Challenges of today



Potential for

- **Conflicting evidentiary and analytical standards**
- **Duplication of effort**
- **Delayed patient access**

What can be done?

What are we aiming for?

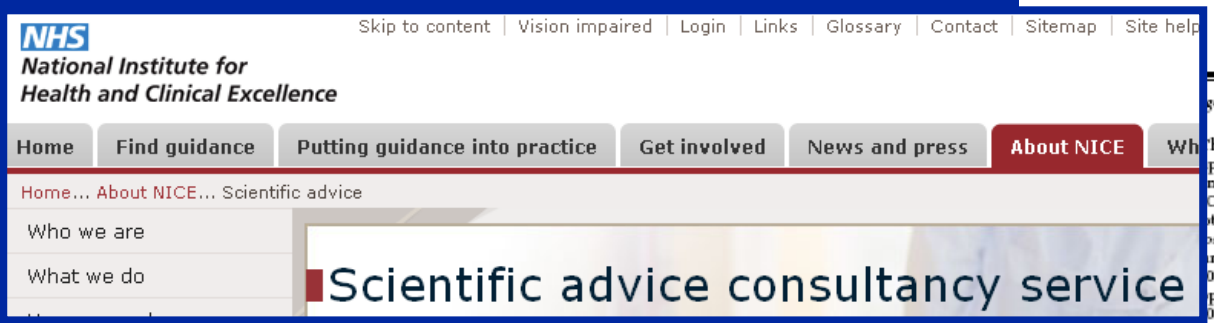
"Reasonable" clinical evidentiary and analytical standards

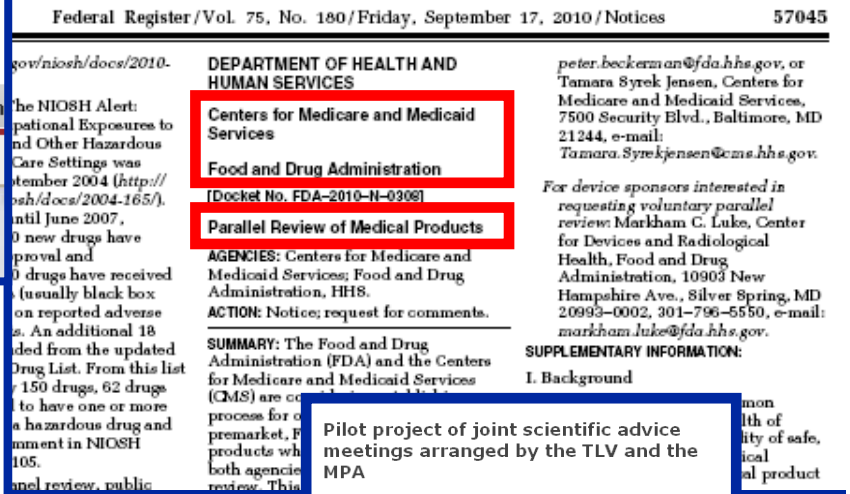
- Validity
- Relevance
- Transparency
- Predictability
- Feasibility

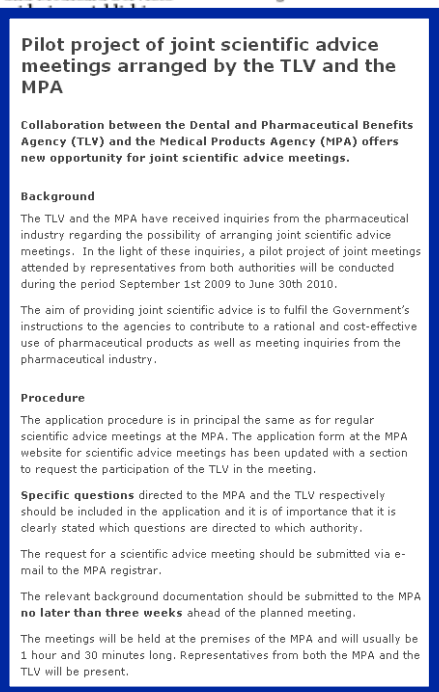
…but that's easier sad than done

Regulators and payers have started to collaborate

Isolated pilots or phase I of constructive engagement?







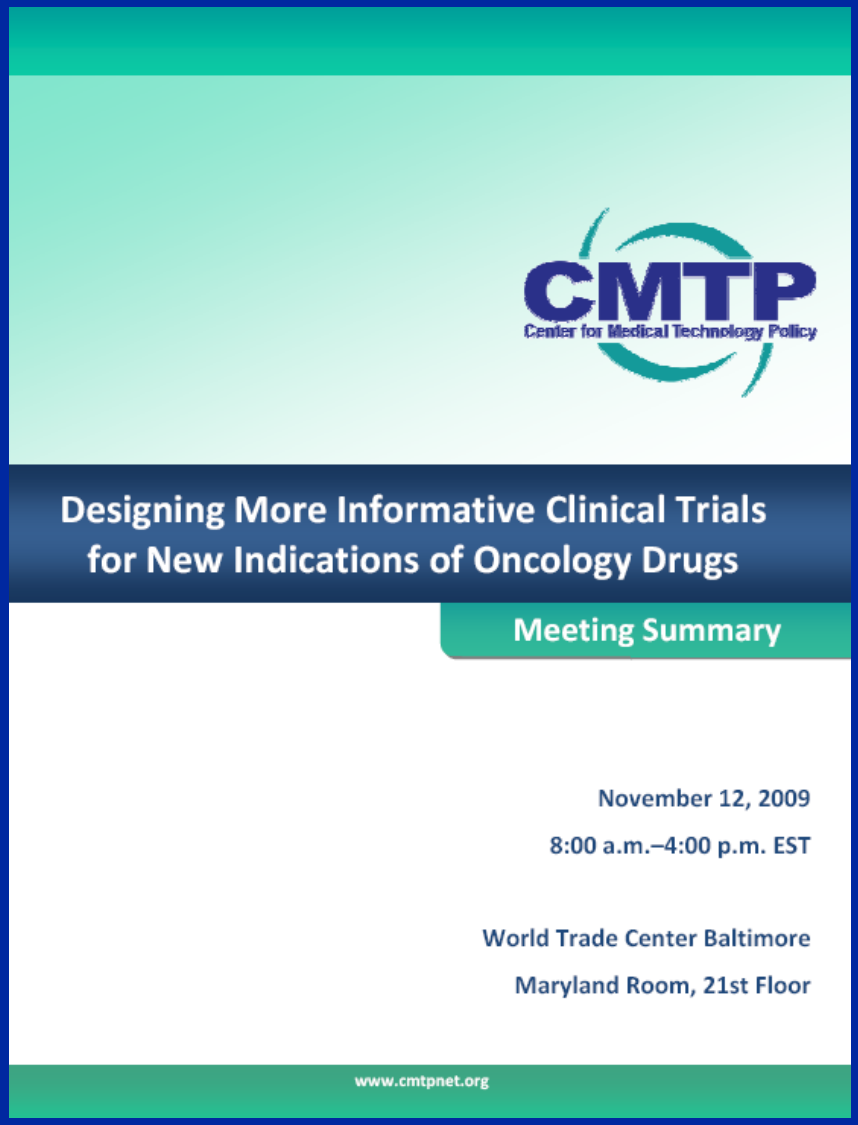
Comprehensive stakeholder involvement

The European pilots

"…committed to addressing the complementary goals of improving patient health outcomes and enhancing the climate for innovation while acknowledging pressures to control healthcare costs"

Comprehensive stakeholder involvement

"Balancing validity, relevance, and feasibility"



Representation of all relevant stakeholders

- Academia
- Patient Associations
- National Research Programs
- Payers (US CMS and private, NICE, PBAC, CADTH)
- Regulators
- Manufacturers

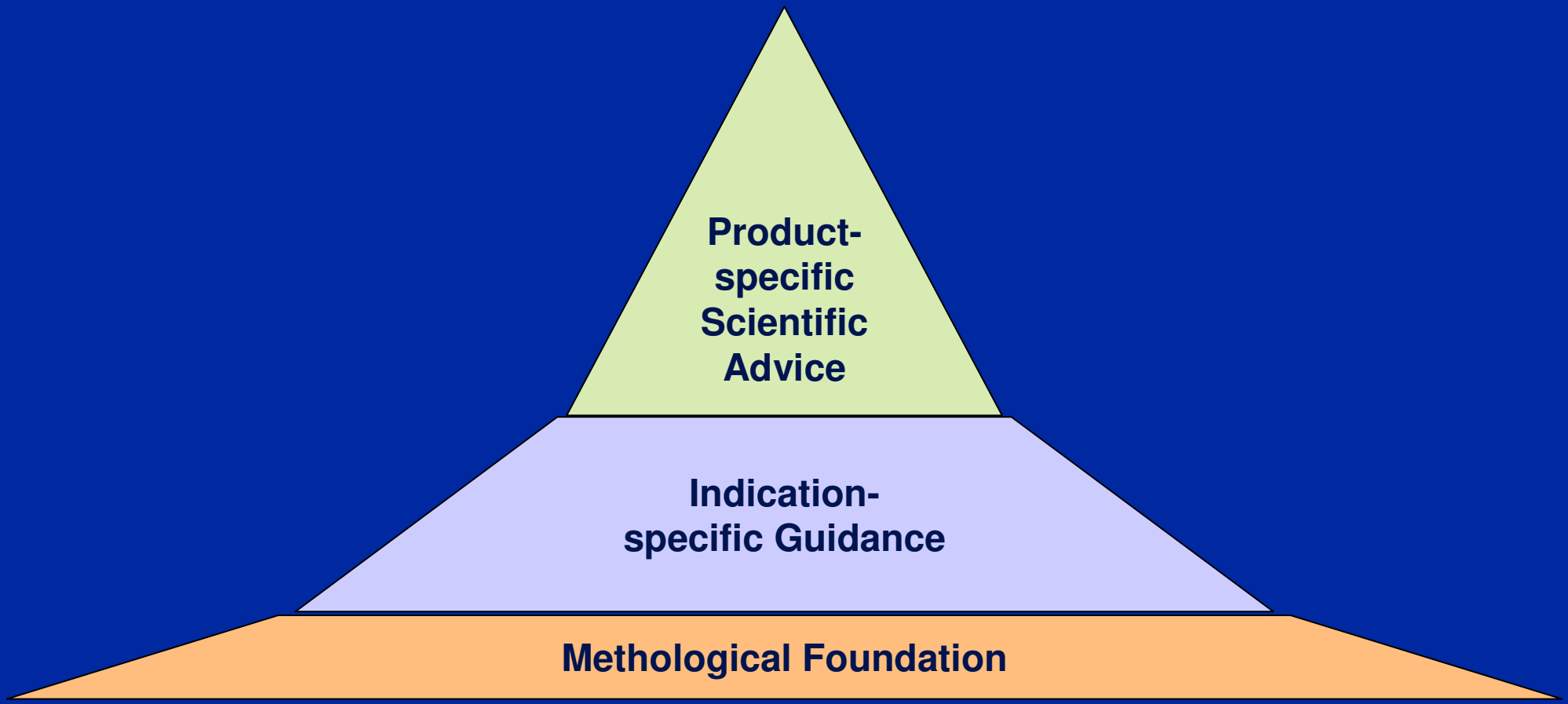
"Reasonable" evidentiary and analytical standards
What does it need?

1. Sustainable platform(s) to promote inclusive involvement of stakeholders (manufacturers, patients/providers/regulators and payers) and (other) experts
2. Shared interest of all stakeholders to establish "reasonable" standards i.e. to balance relevance, validity, and feasibility
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

…plus a much stronger sense of urgency

Good intentions exist - but action is needed

Subject layers of interest



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