



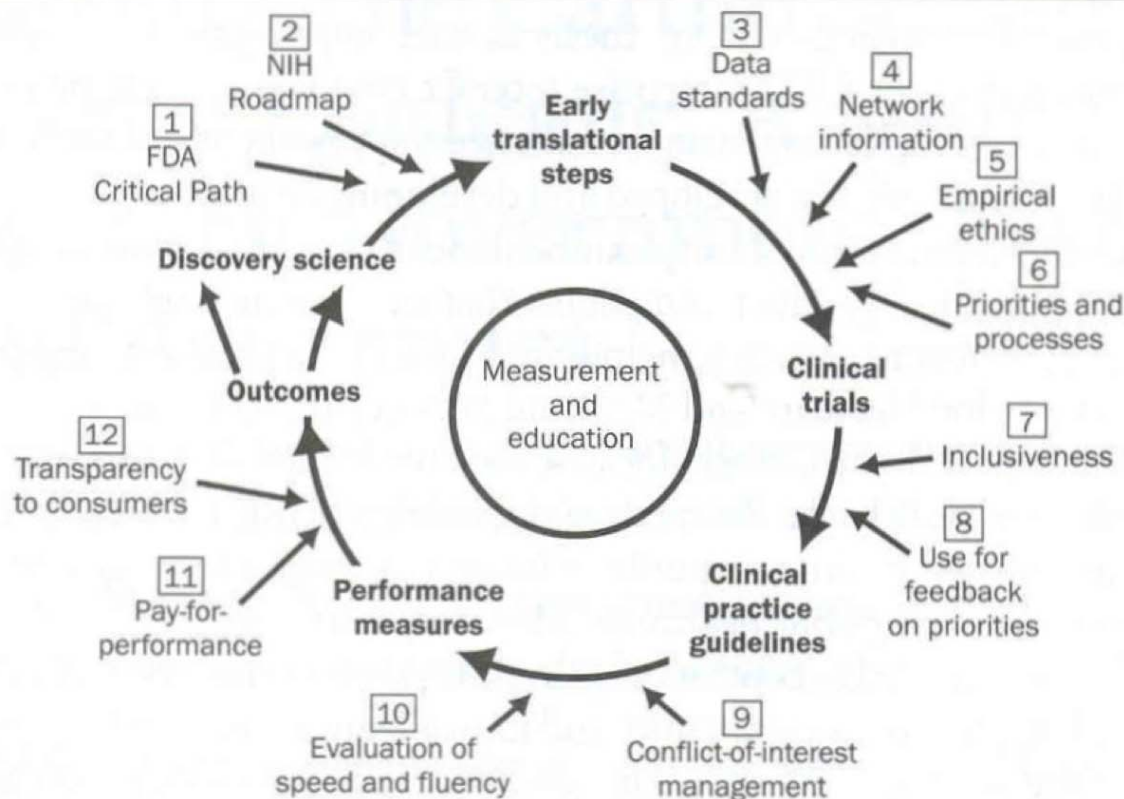
European Federation of Pharmaceutical  
Industries and Associations

# Public Private Partnerships in drug development

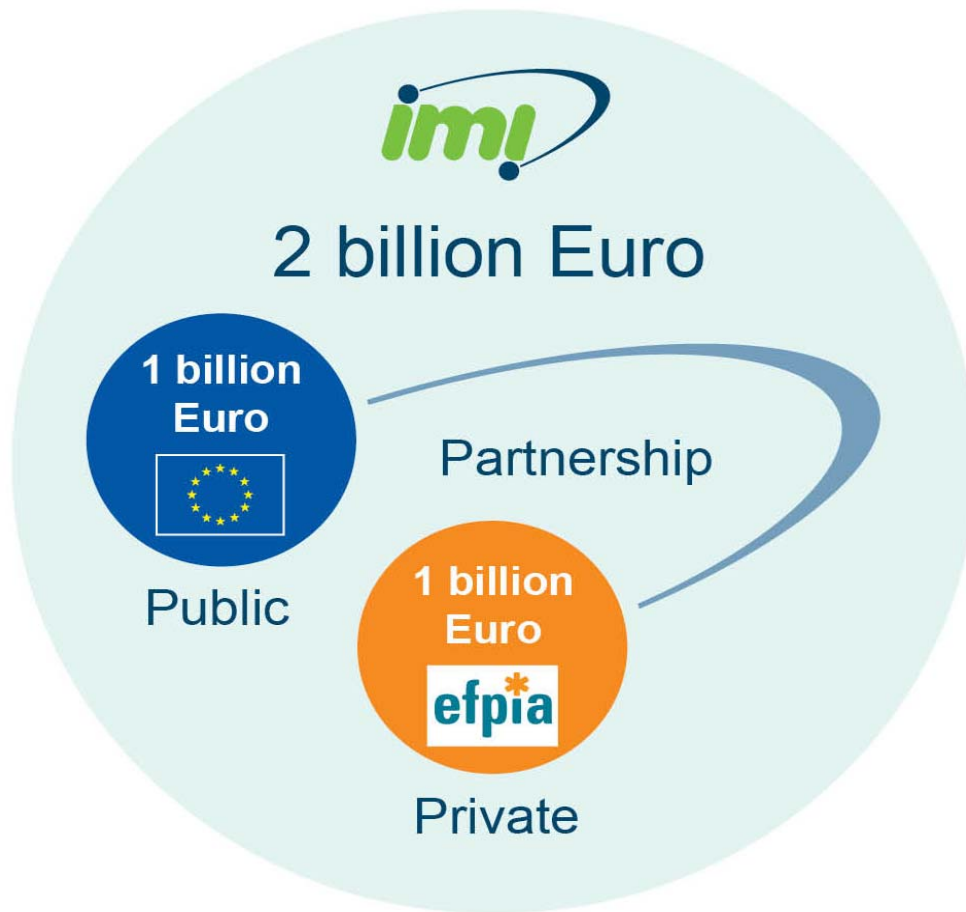
Richard BERGSTRÖM  
EFPIA Director General

PML Workshop London, 25-26 July 2011

## EXHIBIT 1 The Cycle Of Quality: Twelve Steps



**SOURCE:** Adapted with permission from R. Califf et al., "Integrating Quality into the Cycle of Therapeutic Development," *Journal of the American College of Cardiology* 40, no. 11 (2002): 1895-1901.



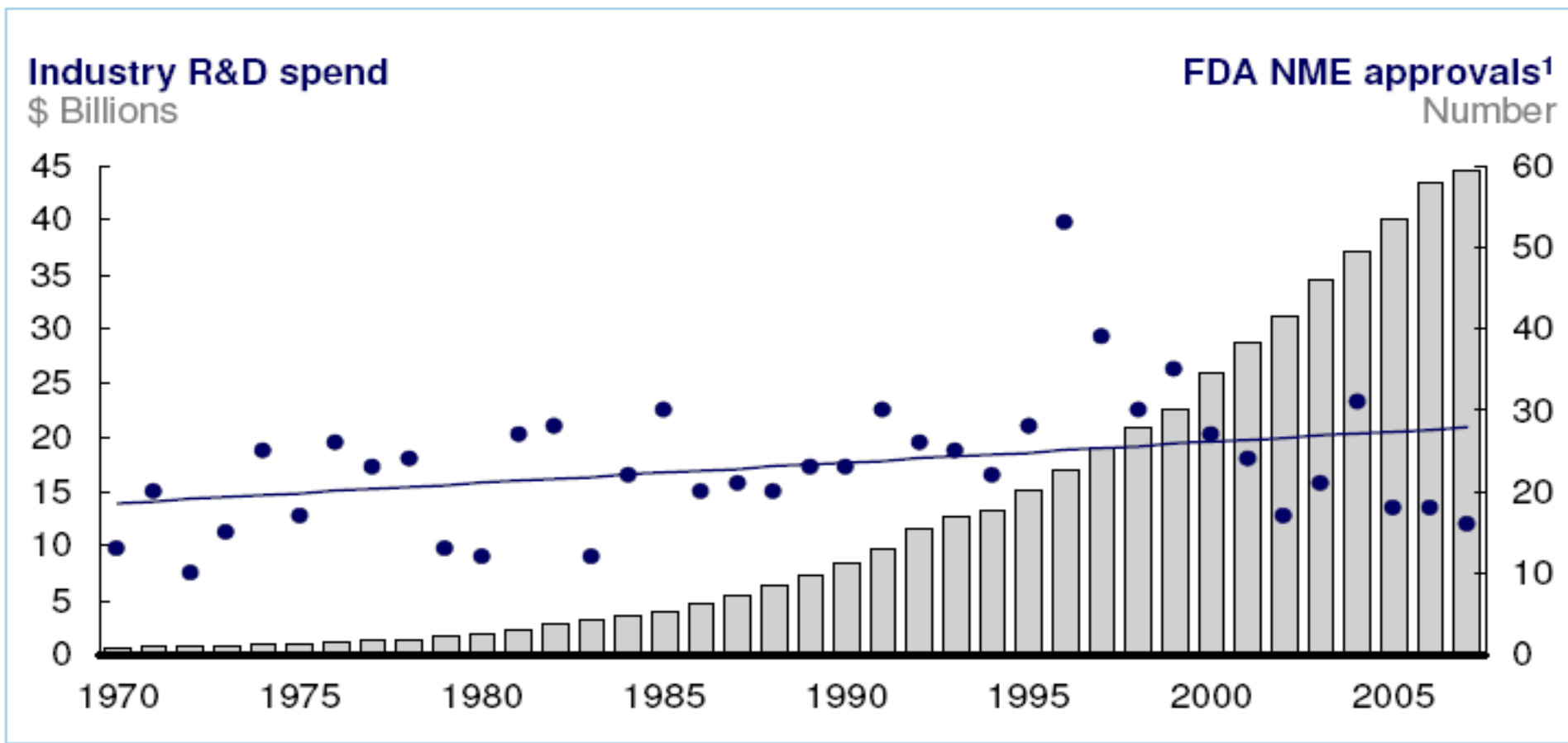
The **European Union** and the  
**pharmaceutical industry**  
have joined forces to make  
**drug R&D processes in Europe**  
**more**  
**efficient and effective**  
and enhance Europe's  
**competitiveness in the sector.**

---

# The challenge



## R&D EXPENDITURE – OUTPUT RETURN ON INVESTMENT 1970-2007



1 Includes NCEs and BLAs. BLAs included 1996 onward; biologics approvals in prior years assumed negligible

# Vision



Make **drug R&D processes in Europe** more efficient and effective  
and  
enhance Europe's **competitiveness in the sector**



Idea generation

Basic research  
and non-clinical  
testing

Human testing

Regulatory  
approval  
and Health  
Technology  
assessment

Marketed  
drug

To the benefit of EU: Improved healthcare status of individuals and society, and positive economical impact  
To the benefit of Pharma Industry: facilitate development of next generation drugs

# Overview Call 4



## Cluster 1: EU Medical Information System

1. Building up a European Medical Information Framework to improve healthcare and facilitate research
2. ETIKS: European Translational Research Infrastructure & Knowledge Management Services

## Cluster 2: Chemistry, Manufacturing and Control

3. Delivery and Targeting Mechanisms for Biological Macromolecules
4. In vivo predictive biopharmaceutics tools for oral drug delivery
5. Sustainable Chemistry – Delivering Medicines for the 21st Century

## Cluster 3: Technology and Molecular Disease Understanding

6. Human Induced Pluripotent Stem (hiPS) Cells for Drug Discovery and Safety Assessment
7. Understanding and Optimising Binding Kinetics in Drug Discovery

# Current projects - examples

---

- NEWMEDS (schizophrenia and depression; clinical and genetic response data; 20.000+ patients)
  - U-BIOPRED (severe asthma; 38 partners)
  - E-TOX (drug toxicity database)
  - SAFE-T (153 potential biomarker candidates for drug-induced injury of the kidney, liver and vascular system)
-