

Ricerca Clinica e Innovazione Farmacologica

Dr. Marco Scatigna
Direttore Scientifico sanofi-aventis Italia
Direttore Generale Fondazione sanofi-aventis

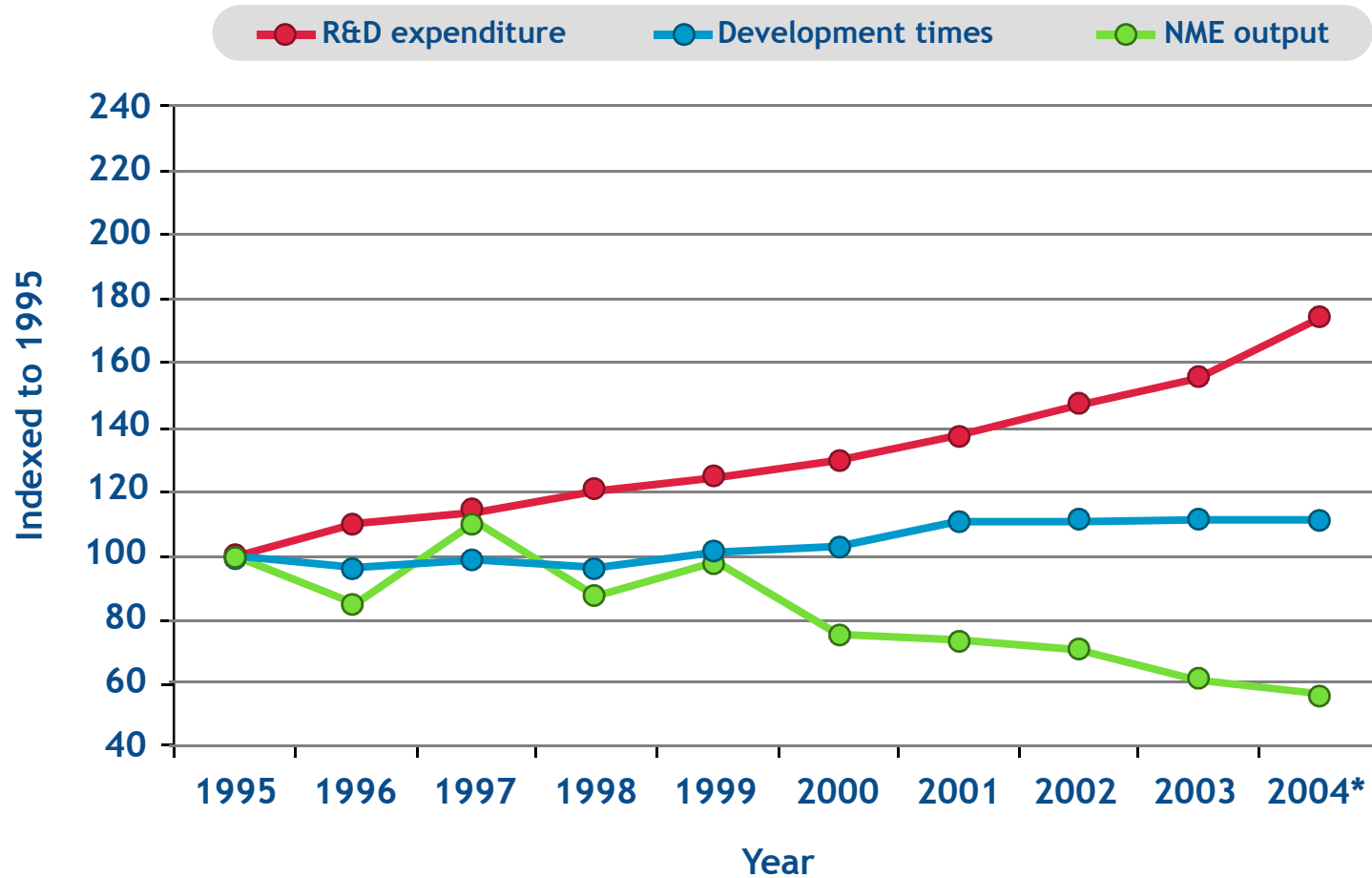


FARMACI INNOVATIVI

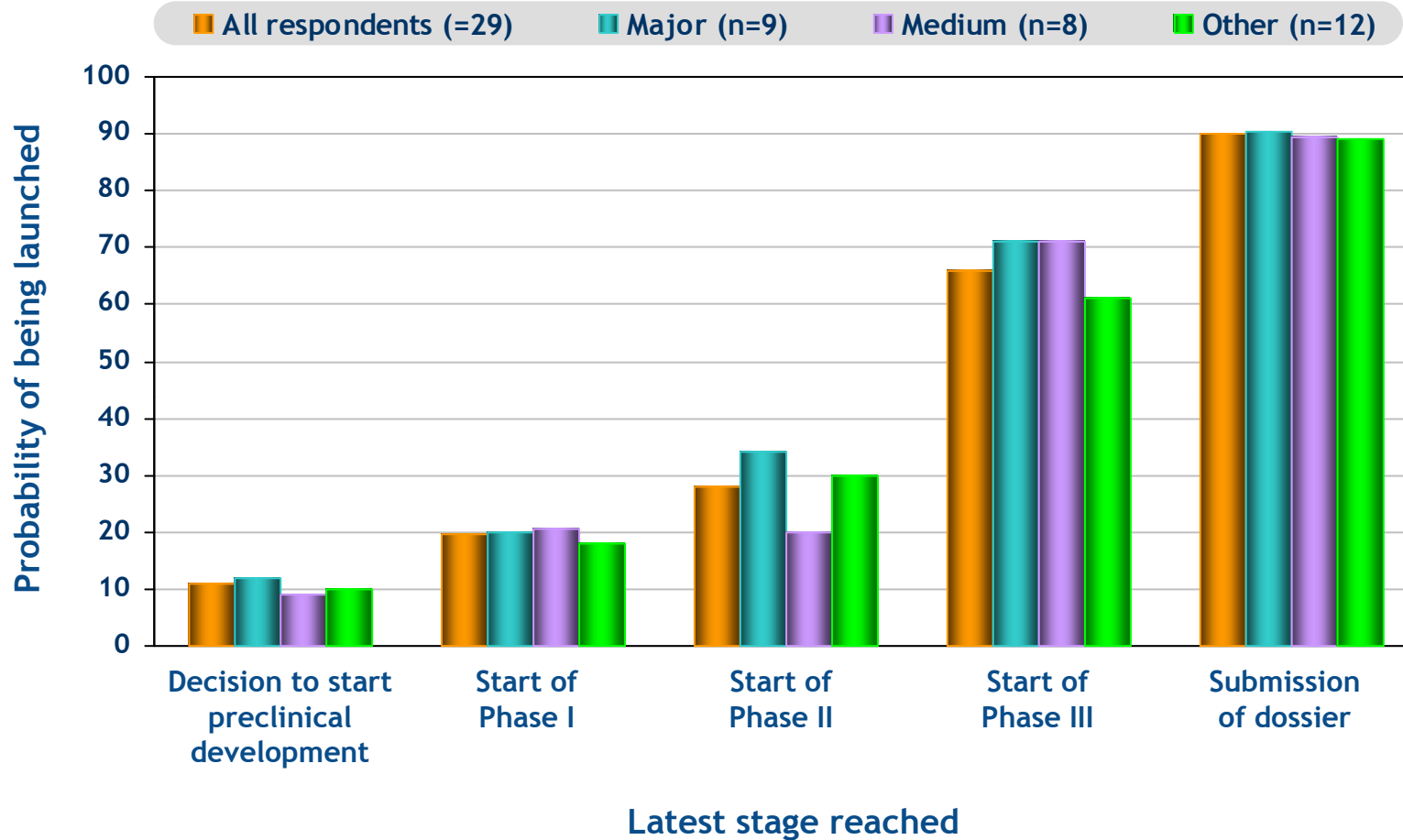
Qualità Efficacia Appropriatelyzza
Garanzia dell'Universalità delle Cure sul Territorio
Nazionale - Farmaci e Dintorni, Spesa o Risparmio
per il S.S.N.?

Roma, Venerdì 5 Giugno 2009

R&D COST, DEV.TIMES, NME OUTPUT FROM 1994 TO 2004

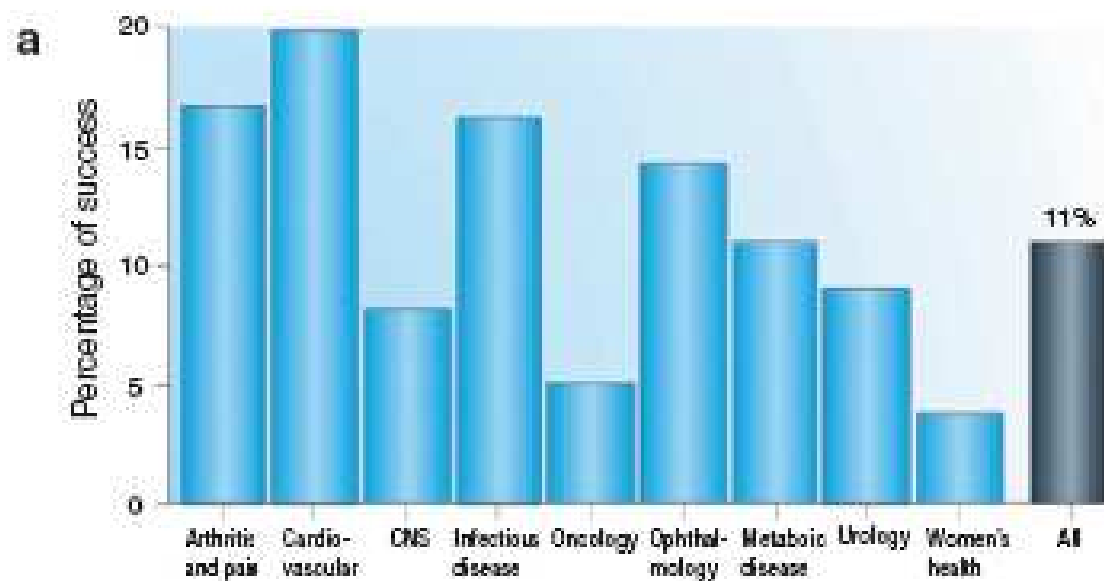


ATTRITION DATA (PROBABILITY OF SUCCESS)

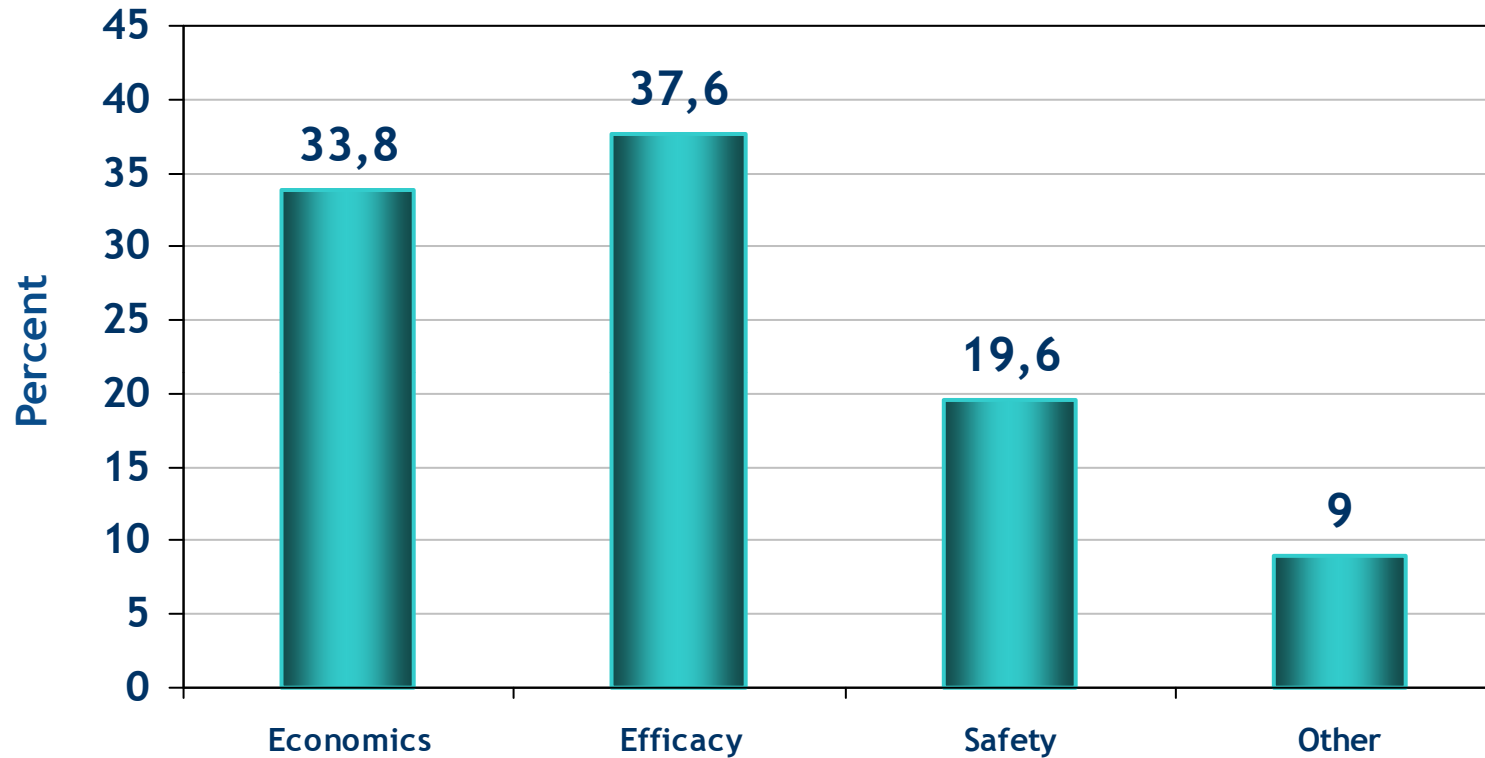


Source: CMR International

SUCCESS RATES FROM FIRST IN MAN TO REGISTRATION



PERCENTAGE OF RESEARCH TERMINATIONS FOR ALL NCEs BY PERIOD OF FIRST IND FILING AND BY PRIMARY REASON FOR ABANDONMENT



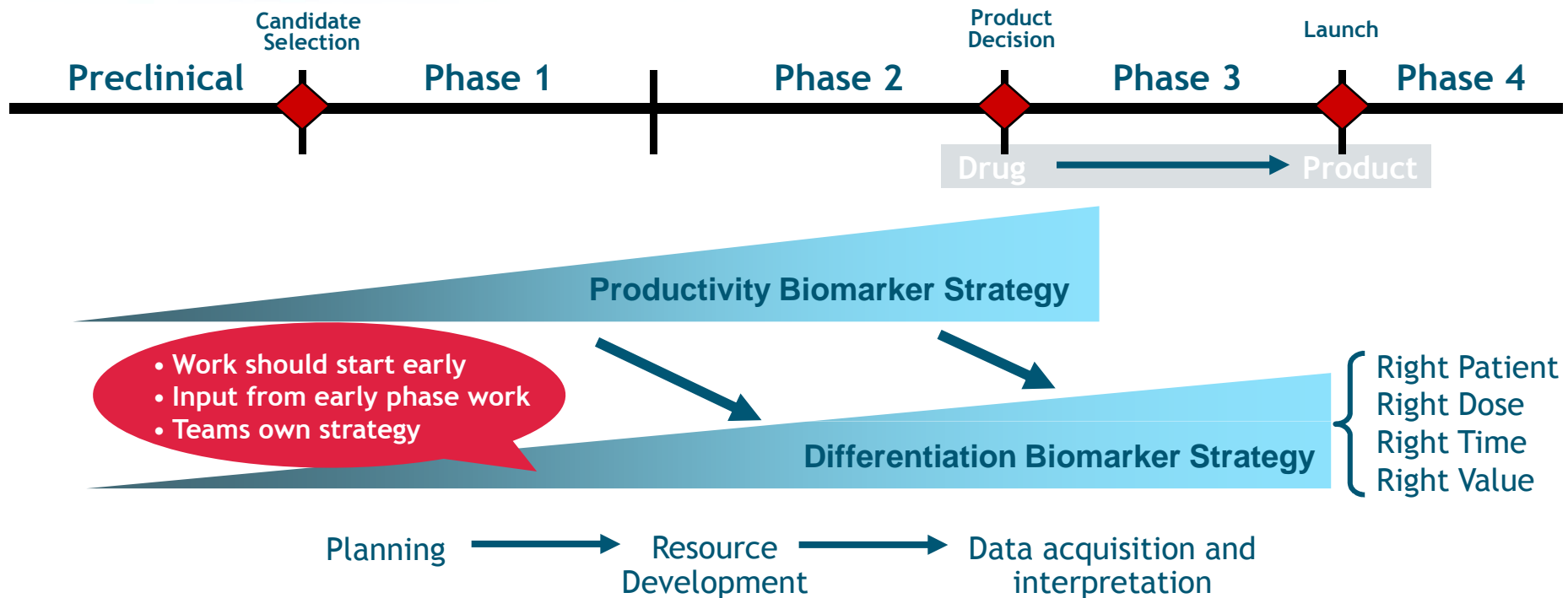
Source: DiMasi, Clinical Pharmacology & Therapeutics, May 2001

“ Compounds targeting novel mechanisms fails more frequently than those targeting precedented mechanisms”

I. Kola

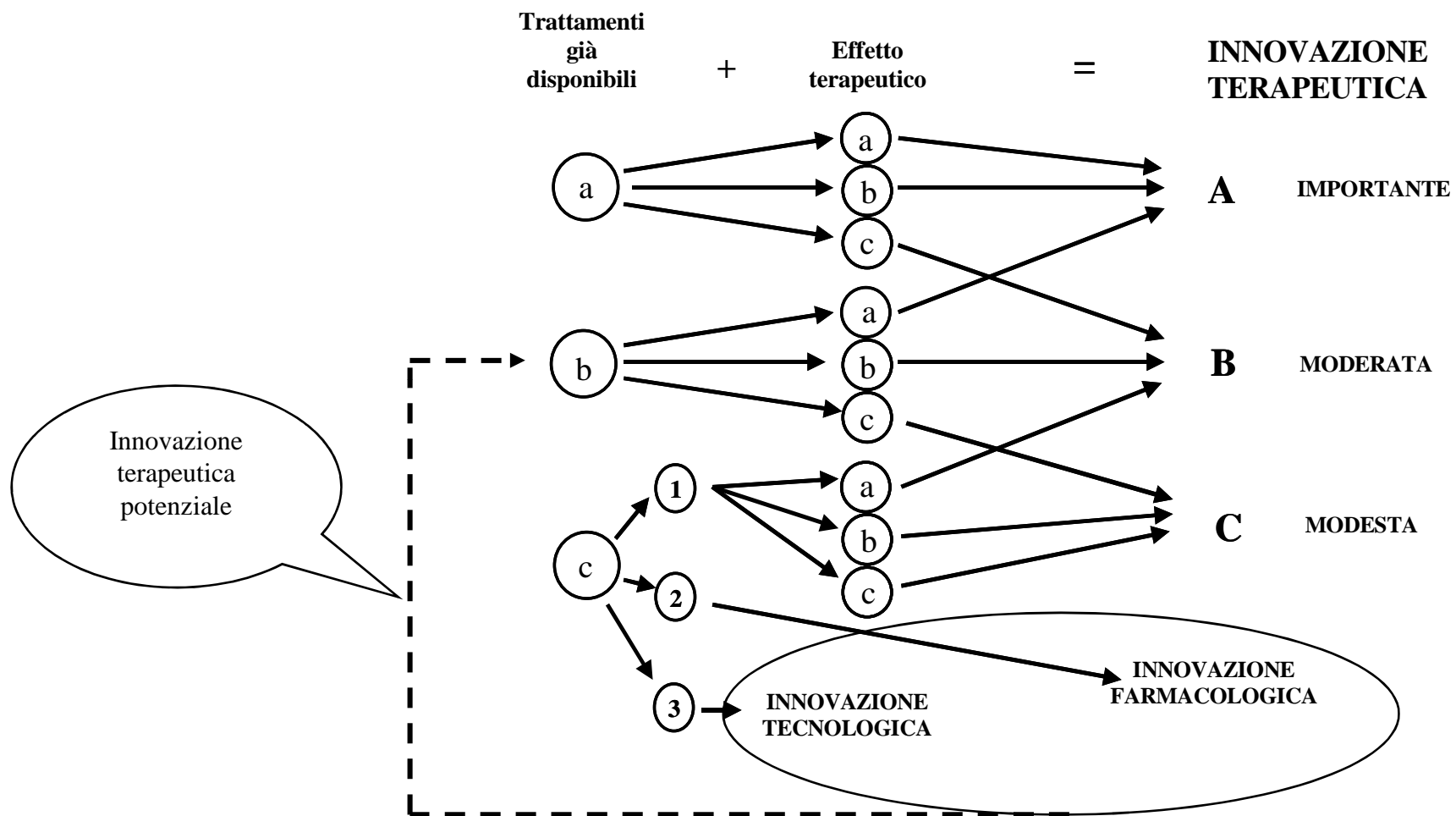
Clinical Pharmacology & Therapeutics 83, 2, 2008.

BIOMARKER FOCUS DURING DRUG DEVELOPMENT: DIFFERENTIATION BIOMARKERS



- Differentiation biomarker strategy helps drive value equation for the product; includes companion diagnostics, markers for differentiation, and markers for identification of special populations.
- Helps differentiate from competitor molecules or standard of care
- Impacts label
- Goal: Improve p(TS) for successful commercialization of product

INNOVAZIONE TERAPEUTICA



Developing a paradigm of drug innovation: an evaluation algorithm.

Luciano Caprino and Pierluigi Russo

Department of Human Physiology and Pharmacology, University
“La Sapienza”, Rome

Drug Discovery Today – Volume 11, Numbers 21/22 – November 2006



SUPERIORITY TRIAL VS NON-INFERIORITY TRIAL

- **Treatment groups:** Rt-PA vs streptokinase
- **Diagnosis at inclusion:** Myocardial Infarction patients
- **Primary end-point:** 30-day mortality rate

Superiority trial

Non-inferiority trial

Patient number

20,726 pts
(10,378 vs 10,348)

2,000 pts
(1,000 vs 1,000)

Mortality rate

6,7 % vs 7,3 % → $\Delta = 1,1\%$

6,7 % vs 7,3 % → $\Delta = 1,1\%$

Statistical results

P = 0,0028

P = 0,37

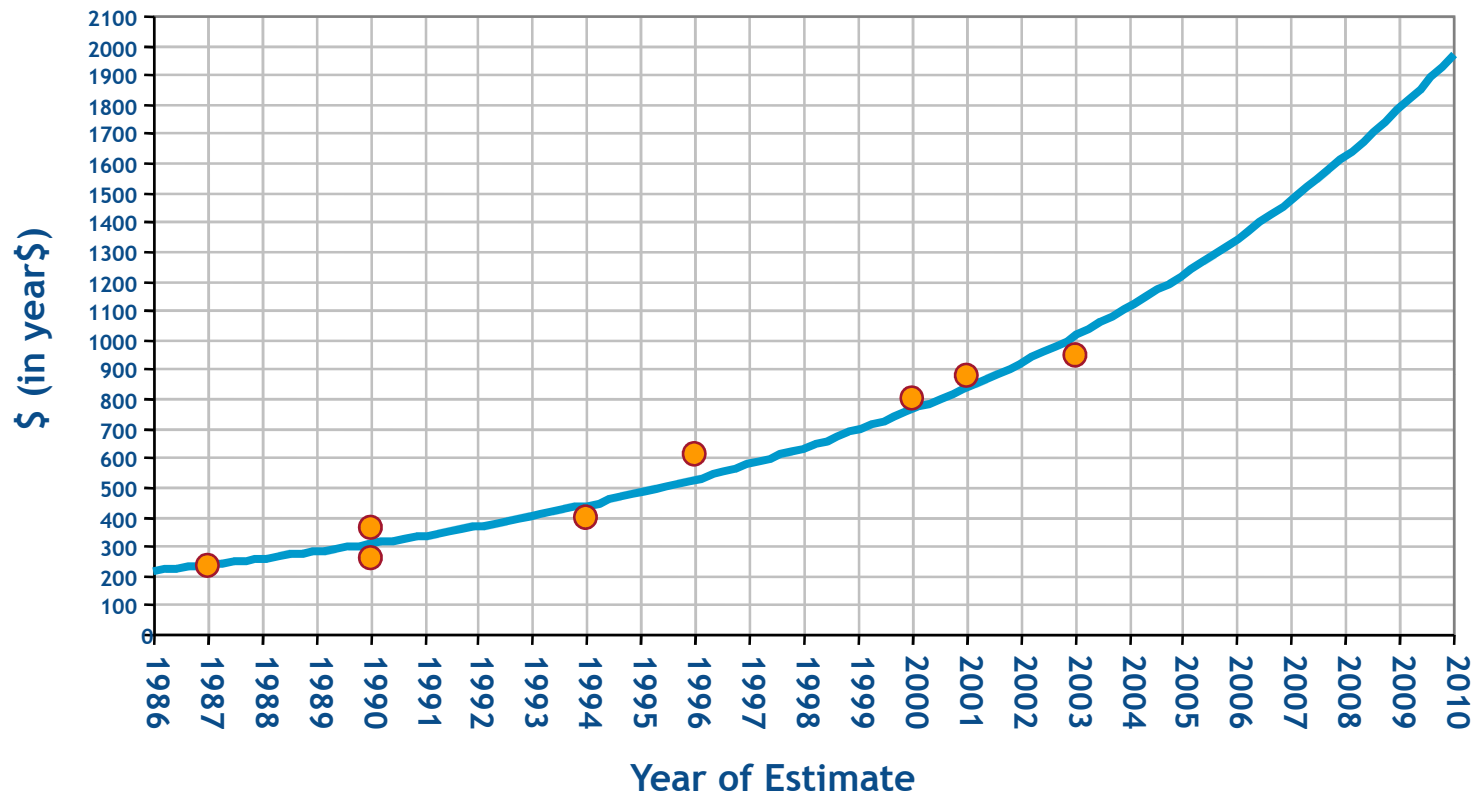
Confidence limits

0,30 % - 1,73 %

1,21 % - 3,21 %

EXTERNAL ESTIMATES OF COST/NME

Cost/NME Launch (not adjusted for inflation) Estimate



Sources: Tufts Center for Drug, Development, Boston Consulting Group, Lehman Brothers