

Trender for kliniske studier - Er Norge konkurransedyktig?

Yngve Mikkelsen

Medical Director / Team Leader

Regional Brand Team

Pfizer PCBU

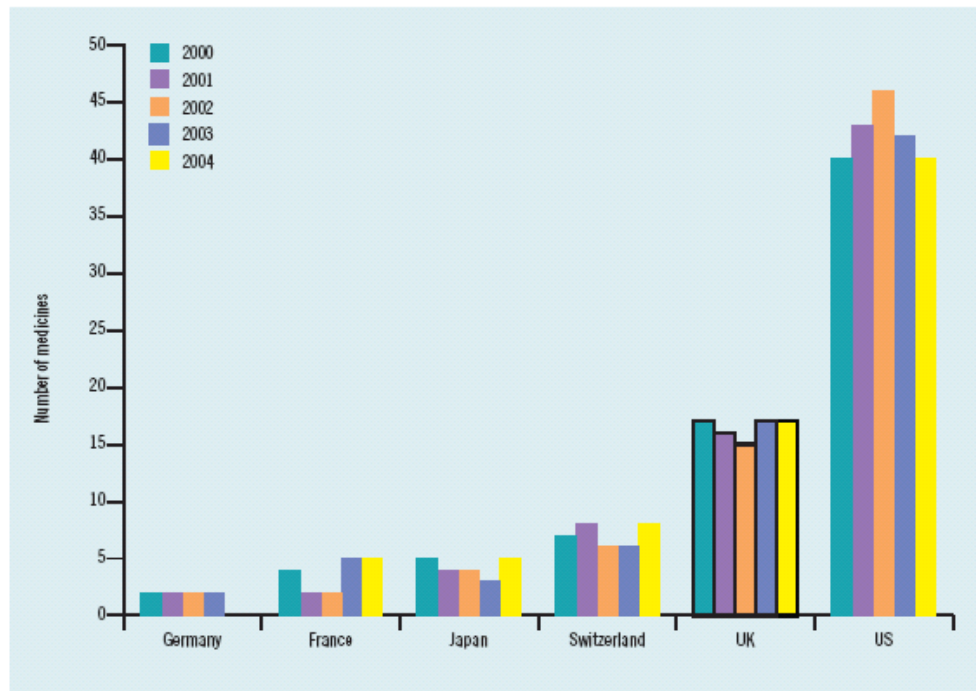
Europe, Canada, Australia & New Zealand



Hvor kommer nye medisiner fra?

Indicator *34: National origins of 'global top 75 NASs'

Chart: National origins of leading 75 global medicines – 2000–2004



Sources: IMS World Review and includes primary and hospital markets



Harvard Business Review 
www.hbr.org



Det er ikke rom for sentimentalitet!

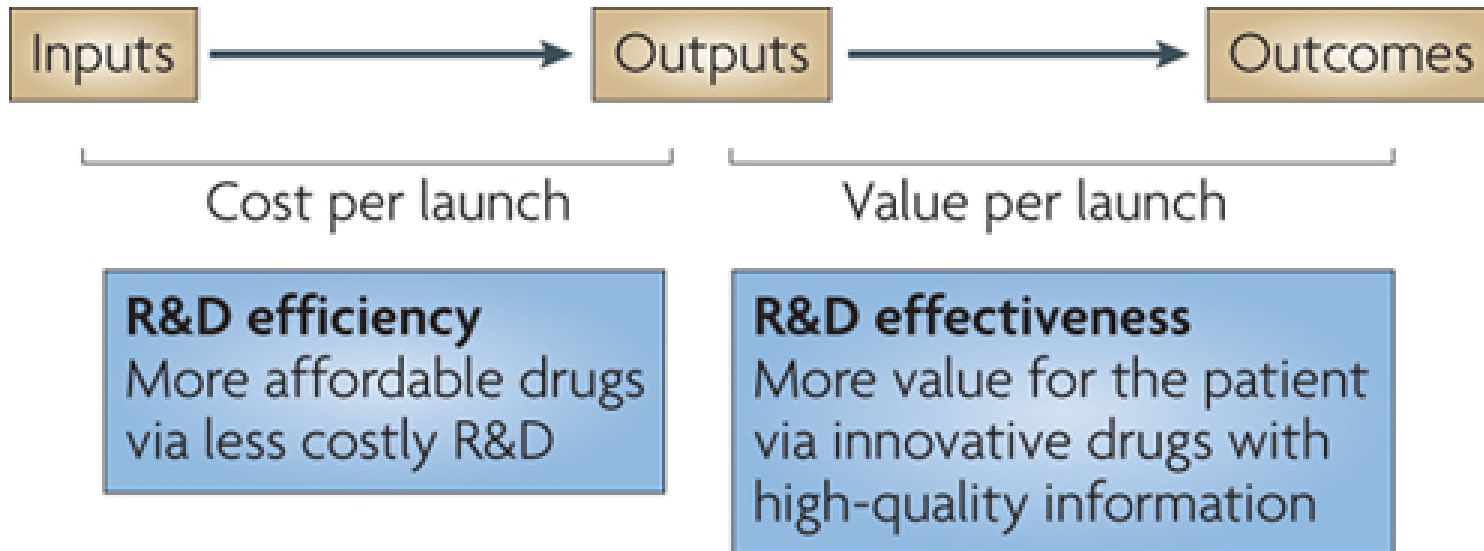
**Beslutninger er stort sett tatt av ledere som ikke er i Norge
og i all hovedsak basert på data fra fortiden!**

“Cap

... Or

Phase III clinical trials ... by switching 50% of its trials from high-cost places such as the United States and Western Europe to low-cost places such as India and South America, a midsize pharmaceutical company with 60,000 patients in clinical trials could save \$600 million annually. (A top-notch academic medical center in India charges \$1,500 to \$2,000 per patient case report, while a second-rate center in the United States charges \$20,000.) ...”

Kostnad/Verdi



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Industrien er under trykk

Compound Attrition

Government
& Payers

Shareholder
Expectations

Escalating R&D
Costs

Decreasing
Exclusivity
Periods

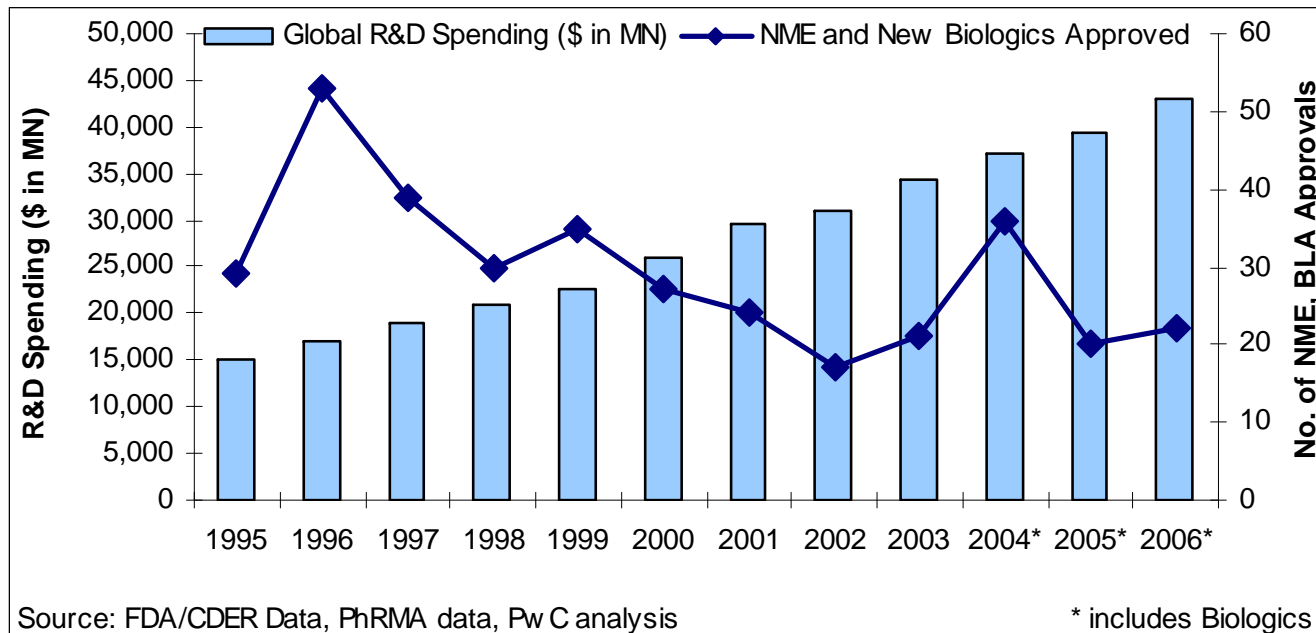
Regulatory
Requirements

Public
Perceptions

Patent Expirations



R&D Produktivitet faller...



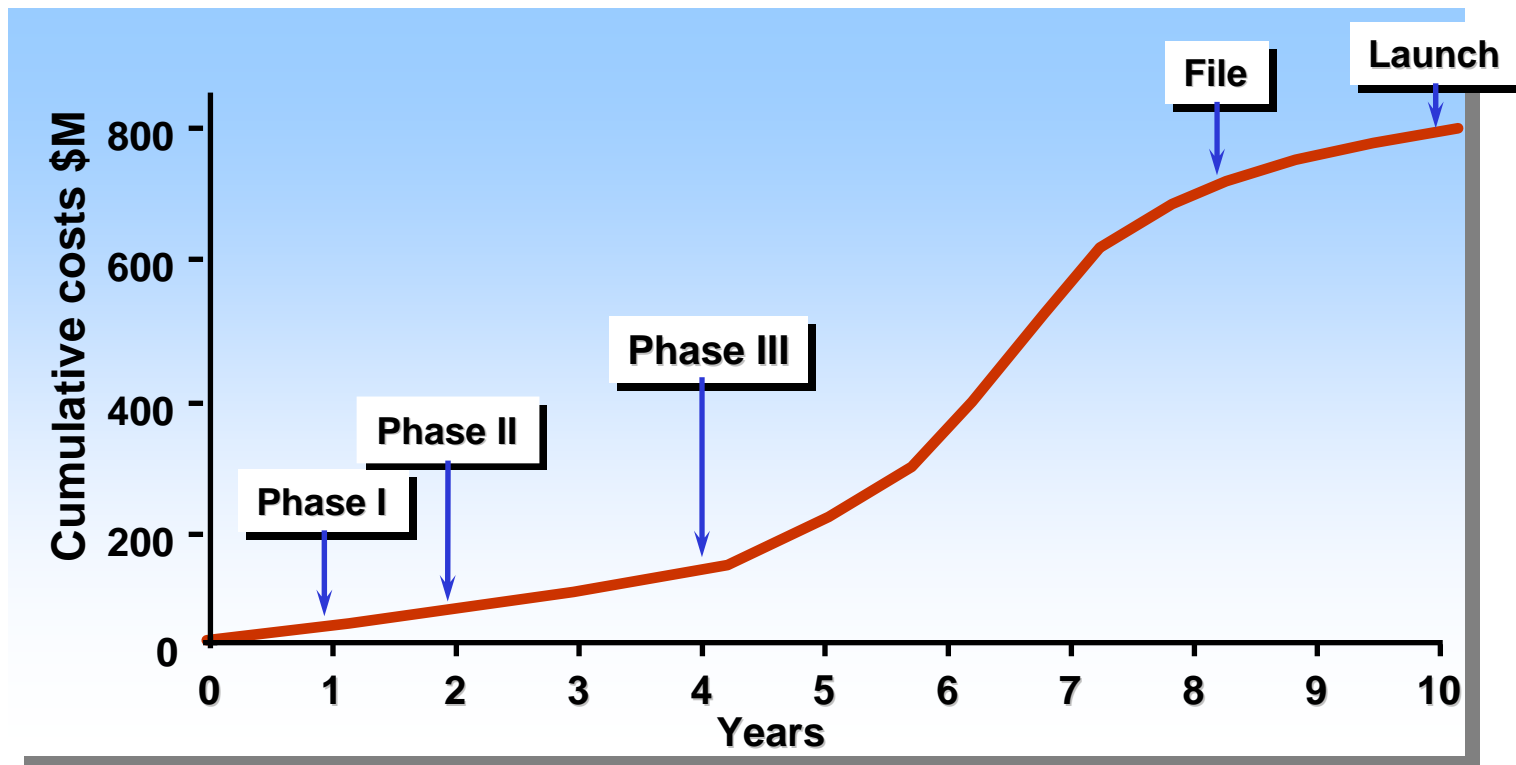
Even allowing for inflation, the industry is investing twice as much in R&D as it was a decade ago to produce two-fifths of the new medicines it then produced.



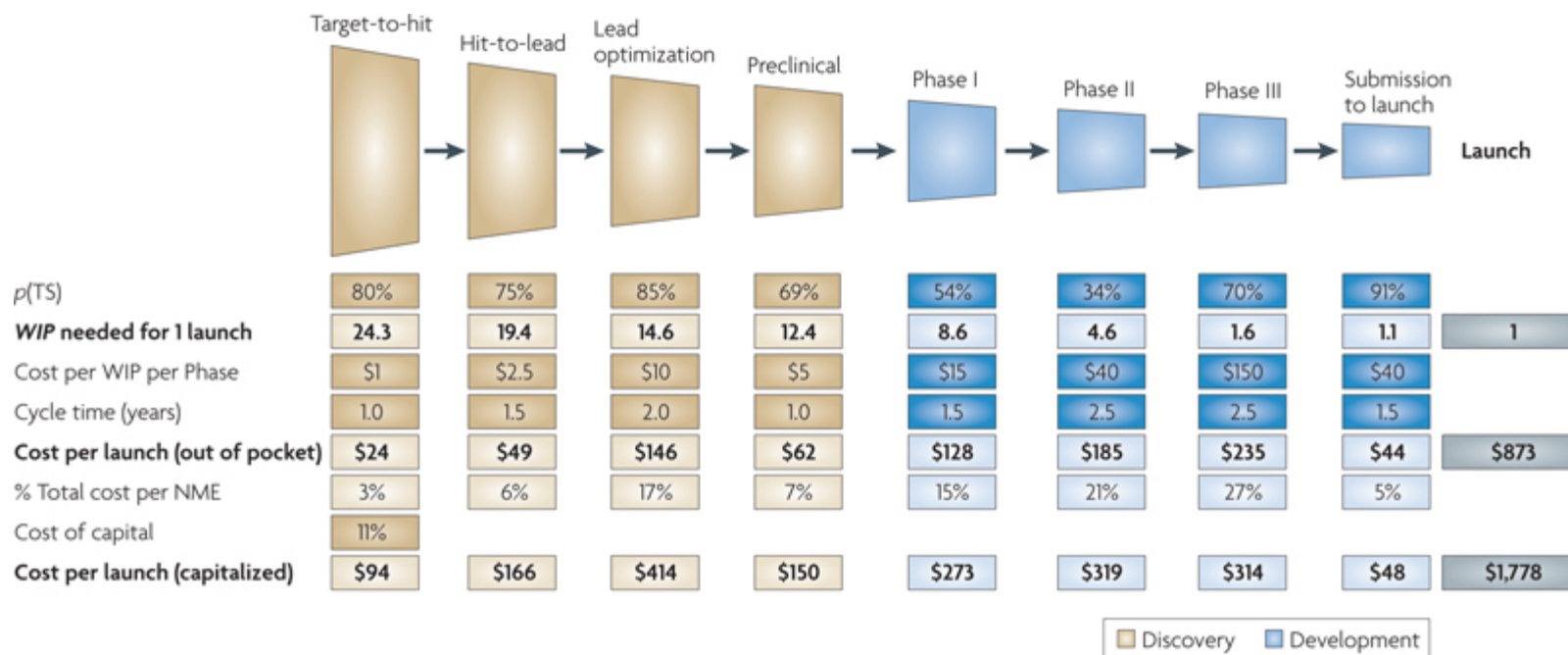
R&D kostnader: Øker signifikant i slutfasen av utvikling

Early stage: focus on attrition

Late stage: focus on cost-effectiveness & preservation



R&D kostnader: Øker signifikant i slutfasen av utvikling



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Hva fokuserer industrien på?

Criterion	Relative importance	Key elements
Strategic relevance	High	<ul style="list-style-type: none">– Value of the market opportunity– Time for product to be launched and accepted in the market– Degree to which key opinion leaders are needed for success
Quality	High	<ul style="list-style-type: none">– Prevalence of desired patient or disease– Availability of skilled physicians and investigators– Domain expertise (e.g., specialty devices, CNS, oncology)– Quality of protocol adherence– Tracking and data systems
Time	High-Medium	<ul style="list-style-type: none">– Approval time (e.g., protocol approval by ethical review boards and regulatory agencies)– Site set-up time– Patient enrolment time– Speed of CRF completion and transmission
Reliability	Medium	<ul style="list-style-type: none">– Ability to forecast delivery against targets– Predictability of delivery against targets
Cost	Medium-Low	<ul style="list-style-type: none">– Trial or clinical investigation costs (e.g., investigator, site overheads)– Level of R&D tax incentives

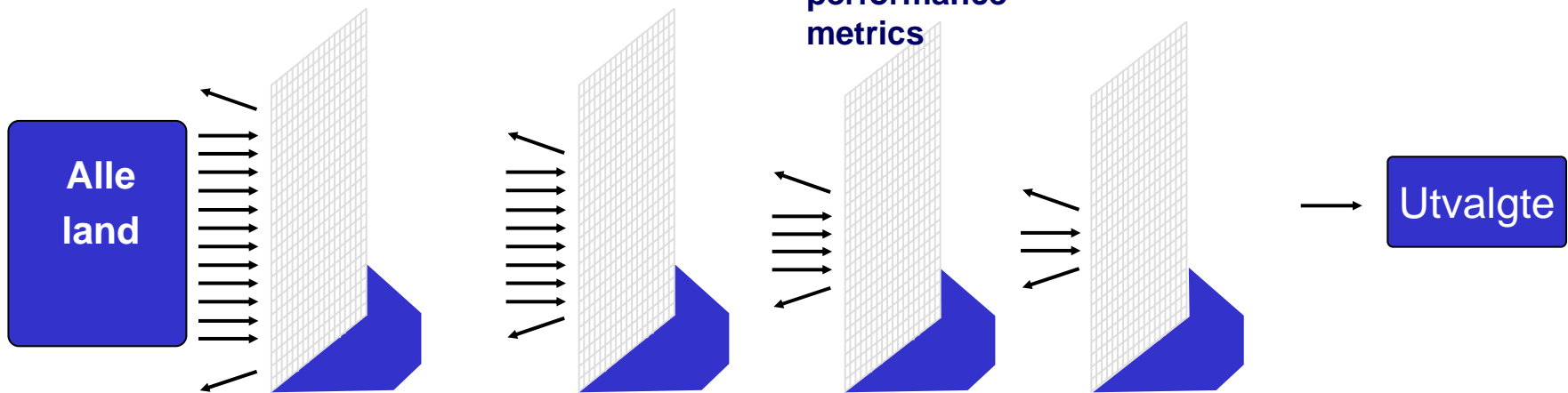
R&D: Utvelgelse

1 Quality and risk filter

2 Population filter

3 Evaluate countries based on performance metrics

4 Prioritize based on quantitative and qualitative analysis



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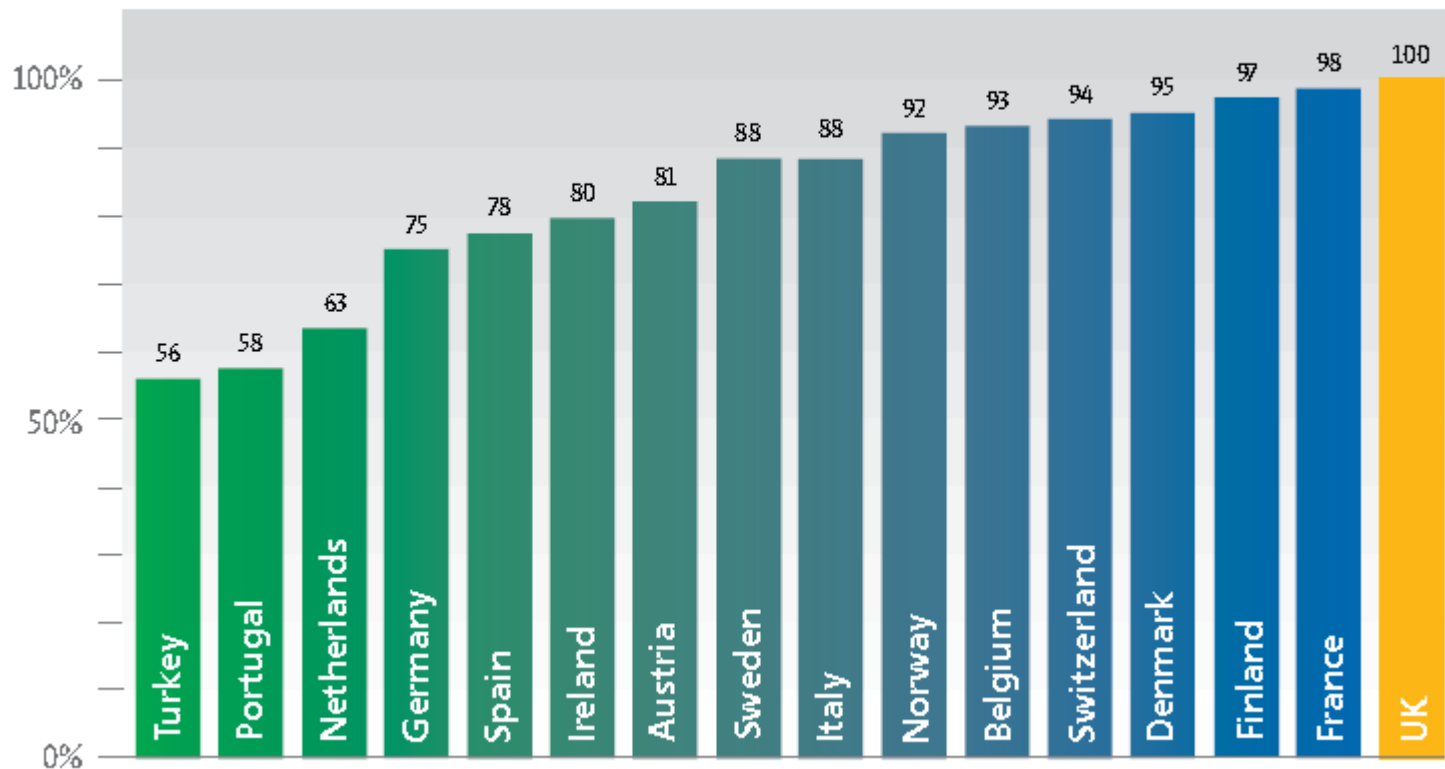
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Relativ kost

The second company did a European comparison of countries in Q2 of 2008 compared with a relative cost of 100 in the UK ⁽¹⁵⁾.



(15) Source: Clinical Directors of UK affiliates of three top-ten global R&D organisations, provided for workshop



Konklusjon: Globale trender

- Globalisering → konsolidering
- Samarbeid mellom firmaene og nettverk
- Stram prioritering → omorganisering
- Universalt fokus på kvalitet, tid og pris
- Kostnadsreduksjon
 - Høyere variabel andel av kostnader
 - Større grad av "outsourcing"
- Reduksjon i total investering i FoU
- Økt investering i "Emerging Markets"



Tid er penger

- Patentbeskyttelse = 20 år
- Utvikling tar 8 – 12 år
- Utvikling koster
- Begrenset vindu for inntjening og reinvestering
- Pris er underordnet kvalitet og tid



Er Norge konkurransedyktig?

- Svaret er
- Avhengig av evne og vilje til å differensiere:
 - Tilgang til pasienter & klinikere
 - Kvalitet
 - Tid
 - Kostnad
- Norge er godt på vei til å bli marginalisert



Takk for oppmerksomheten!

