

Personalized medicine: Bringing Innovation to Market

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Innovation Fund Denmark

RESEARCH, TECHNOLOGY & GROWTH

What is Innovation ?

Innovation = translation of knowledge and insight to value

Value=

- **Profits**
- **Value to patients**
- **Value to Society**

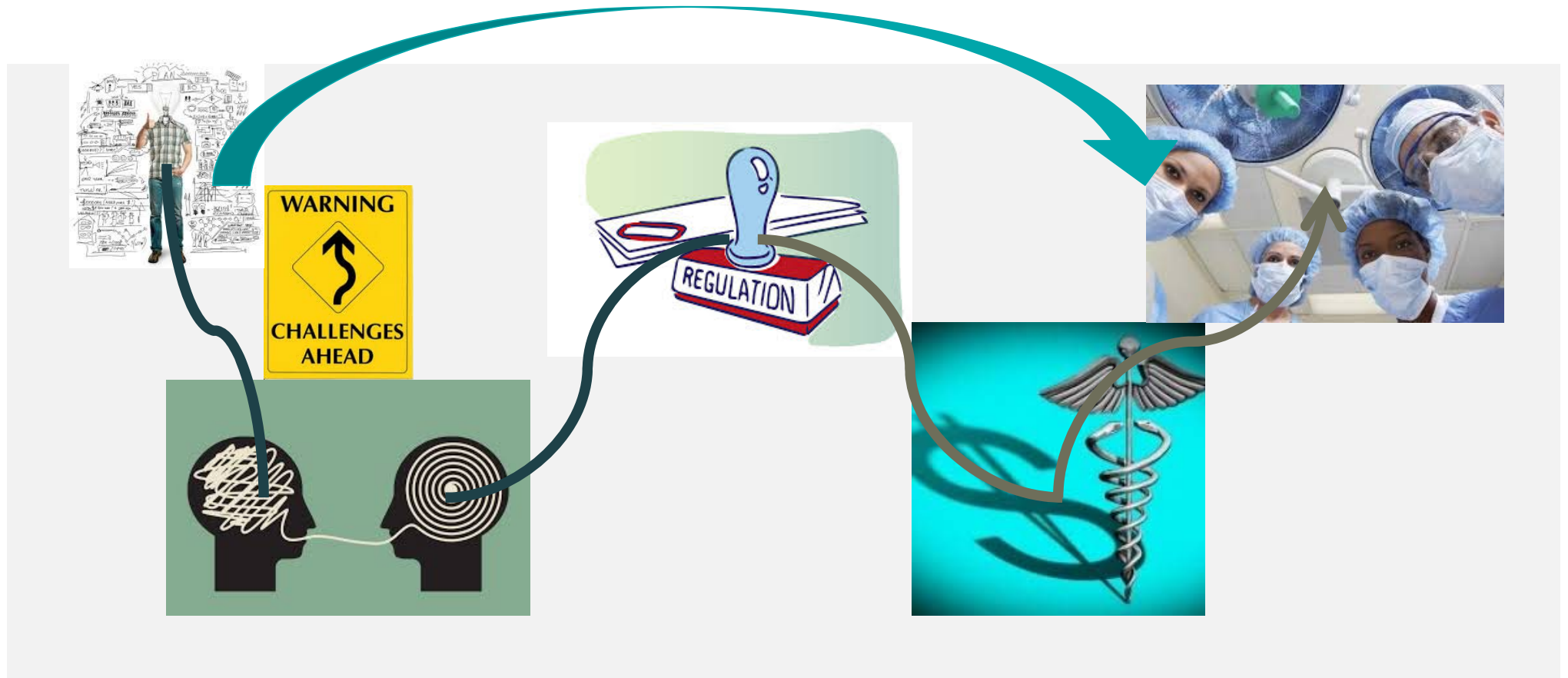


What is Innovation ?

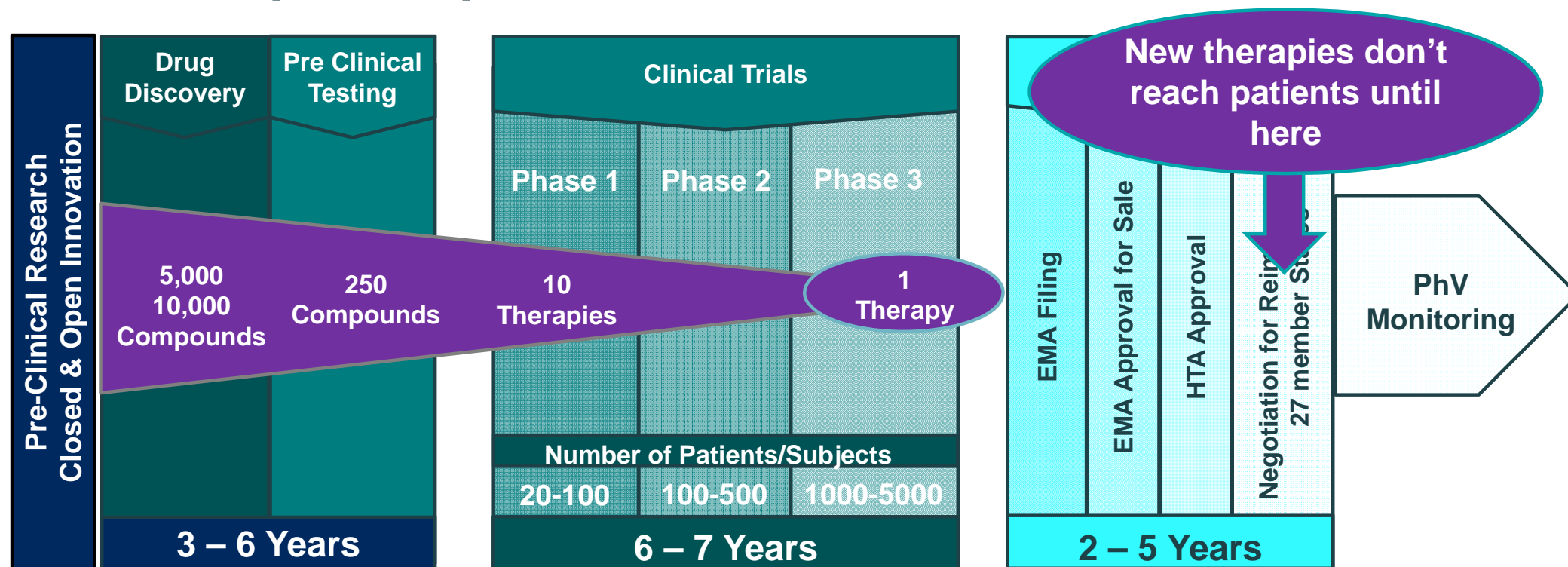
- The process of translation of knowledge (invention or idea) into value
- To be called an innovation, an idea must be replicable at an economical cost and must satisfy a specific need.
- Innovation involves deliberate application of information, imagination and initiative in deriving greater or different values from resources, and includes all processes by which new ideas are generated and converted into useful products.
- In business, innovation often results when ideas are applied by the company in order to further satisfy the needs and expectations of the customers.



Translation from idea and insight to benefit for the patient



Current EU pathways are expensive and slow in getting new therapies to patients



Total Cost: → **\$2 - \$4 Billion USD**

Sources: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org;

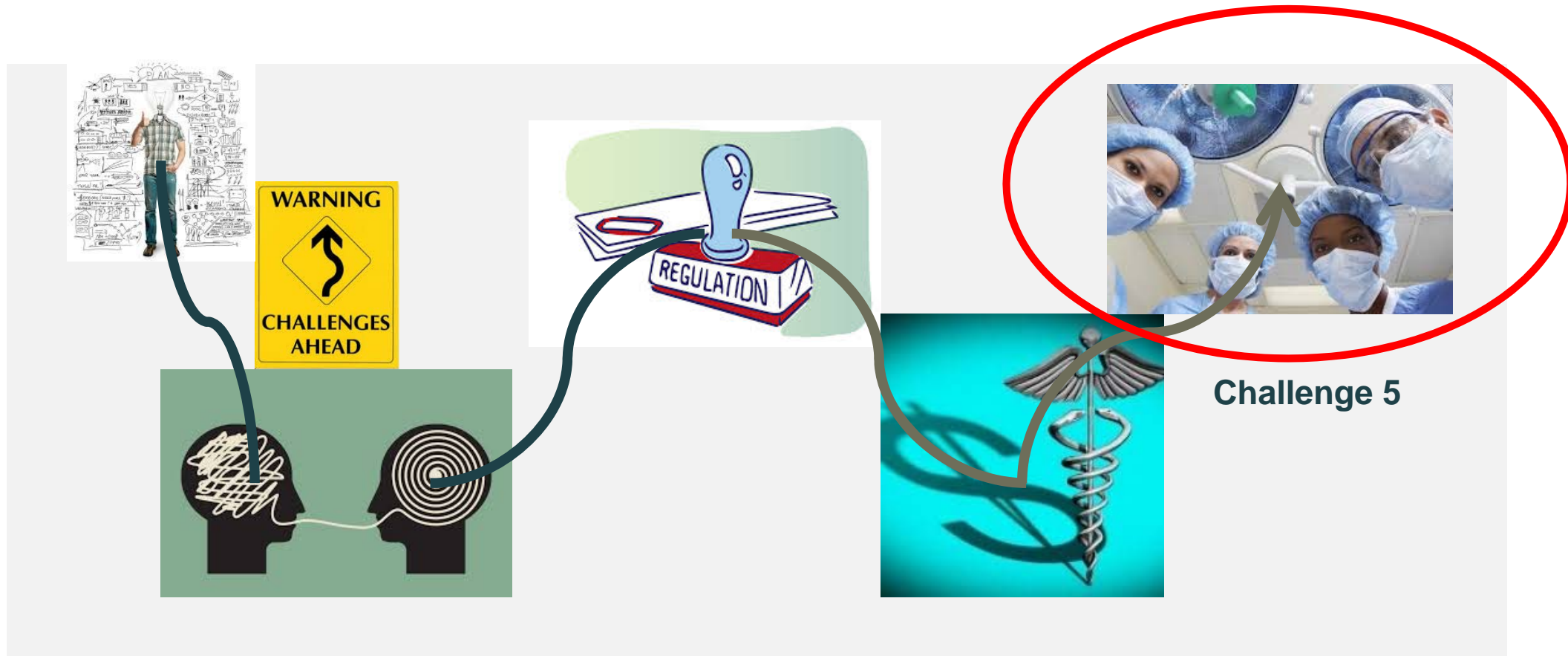
CBO, *Research and Development in the Pharmaceutical Industry*, 2006;

Forbes, [Matthew Herper](#), "The Truly Staggering Cost Of Inventing New Drugs", February 10, 2012

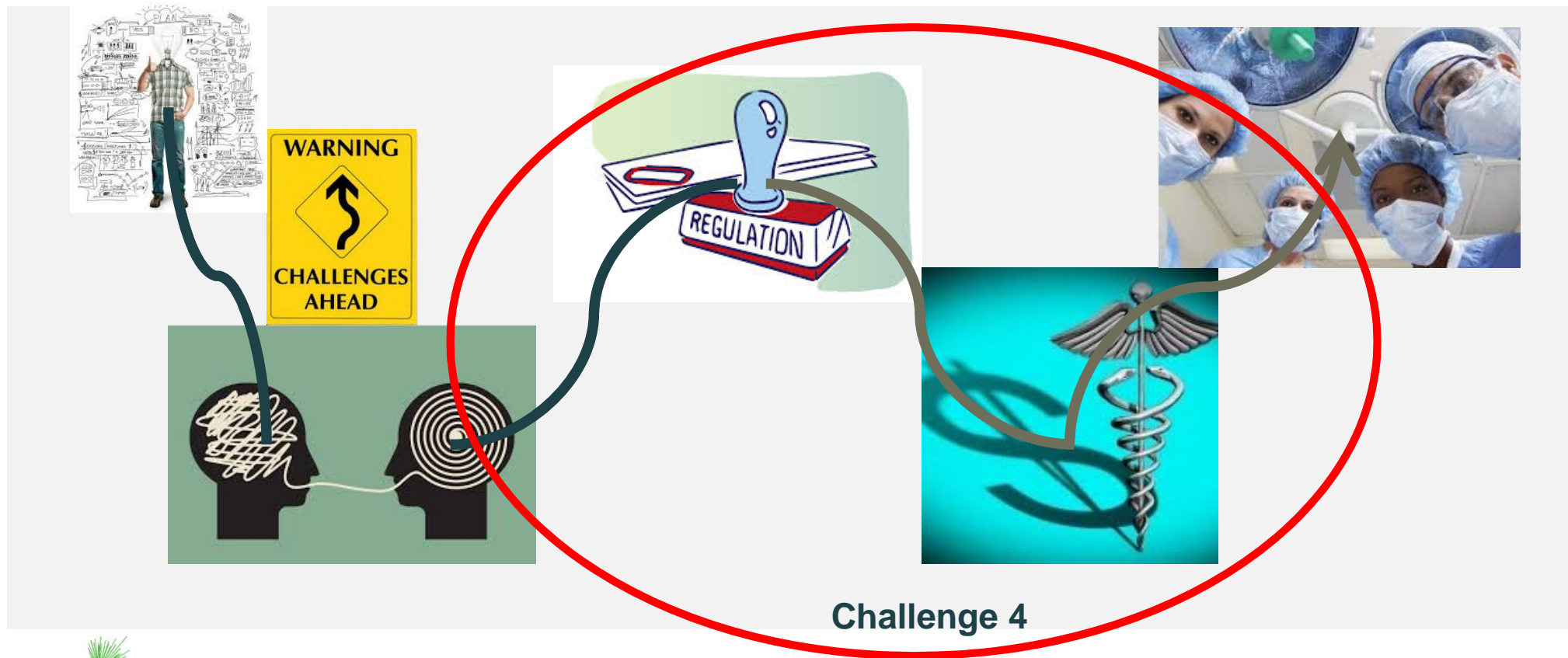
"The average drug developed by a major pharmaceutical company costs at least \$4 billion, and it can be as much as \$11 billion."



Translation from idea and insight to benefit for the patient



Translation from idea and insight to benefit for the patient



How to facilitate and prevent innovation

Get out of the box

- "*Creativity* is thinking up new things. *Innovation* is doing new things."
— Theodore Levit
- "There *ain't* no rules around here. We're trying to accomplish somet'n!"
— Thomas Edison
- "To turn really interesting ideas and fledgling technologies into a company that can continue to innovate for years, requires a lot of discipline." - Steve Jobs

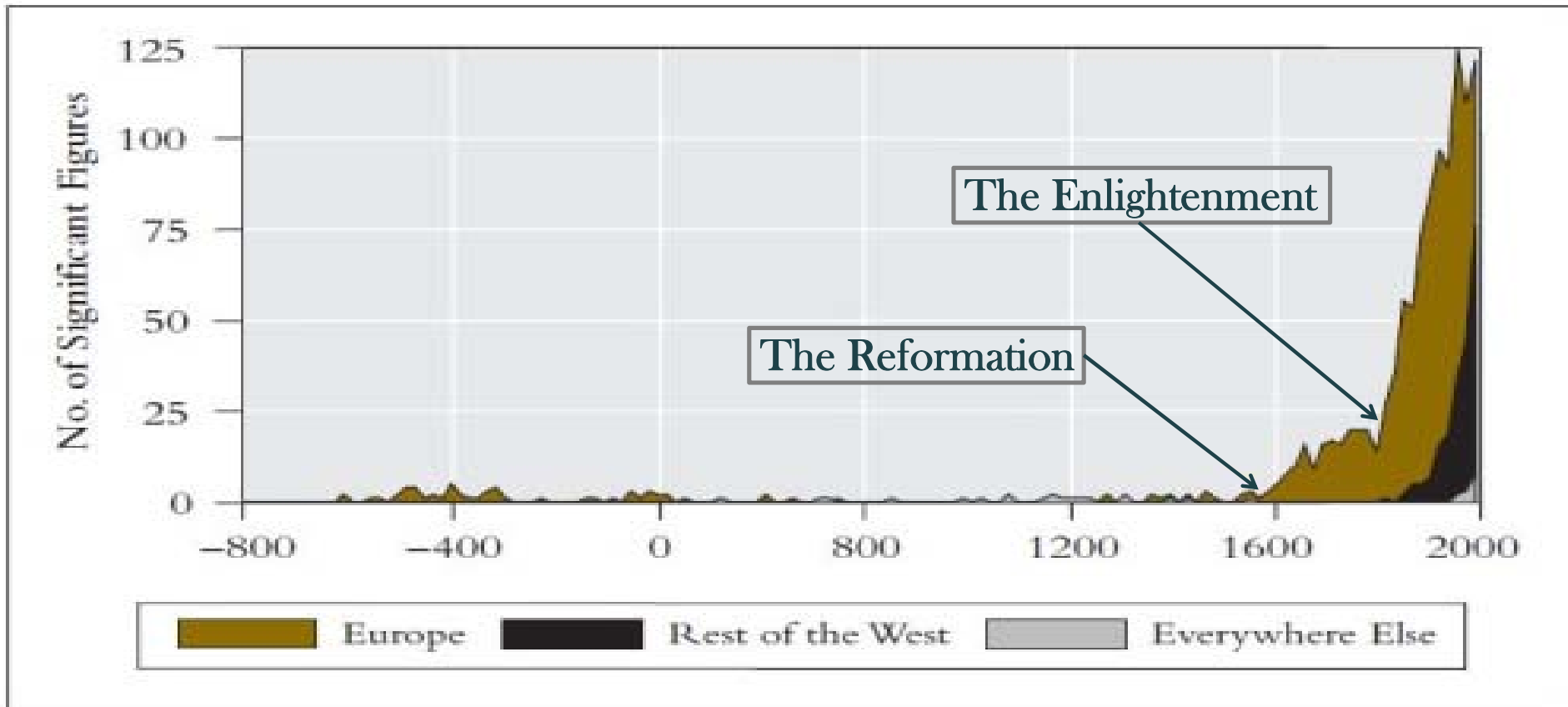
Been there done that

- "Everything that can be invented has been invented."
— Charles H. Duell, Director of US Patent Office 1899
- "Heavier than air flying machines are impossible."
— Lord Kelvin, President, Royal Society, 1895
- "If you want to kill any idea in the world, get a committee working on it." - Charles Kettering



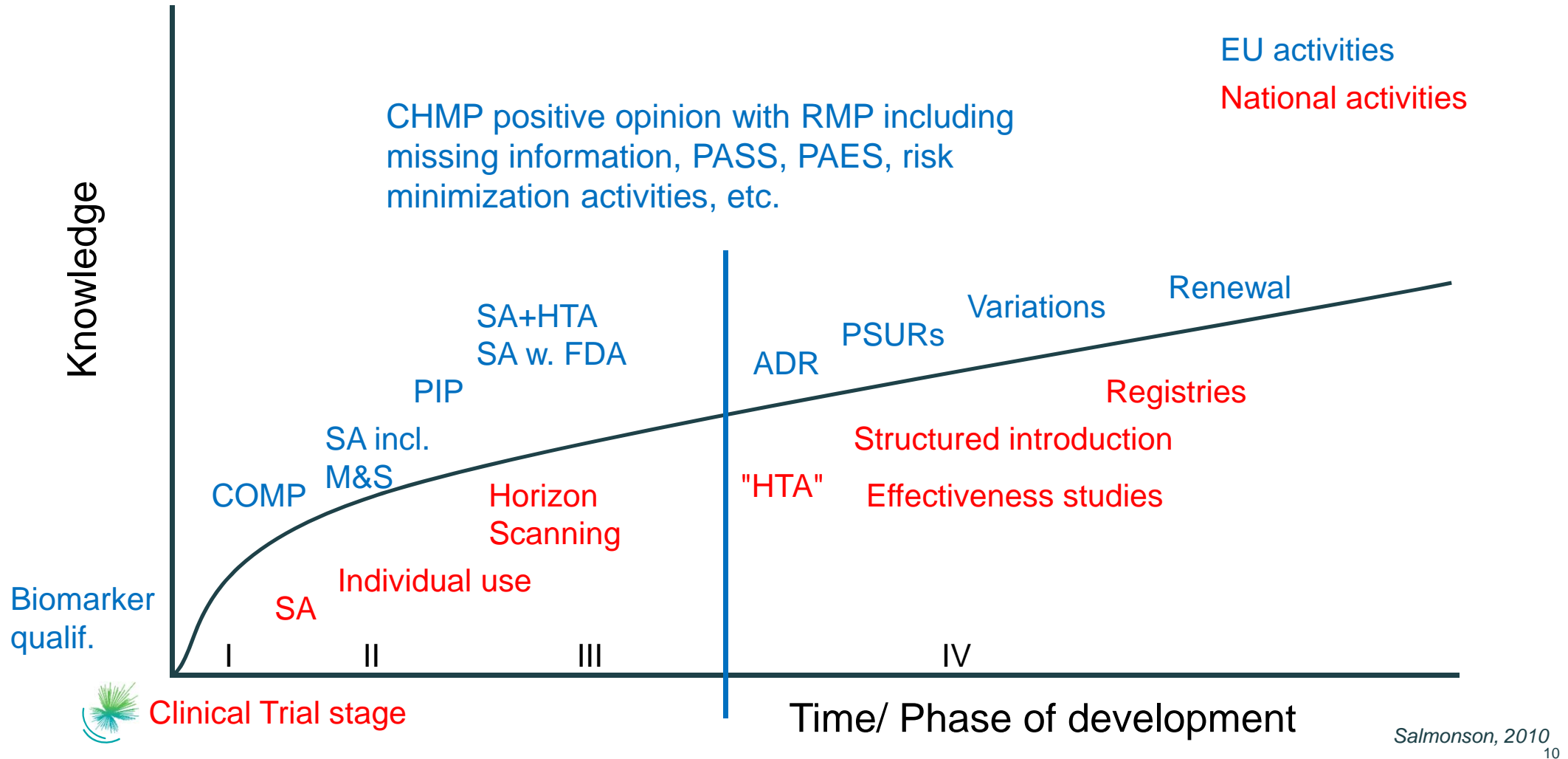
Scientific innovation and influence of societal changes

Significant figures in the scientific inventories
across time and place



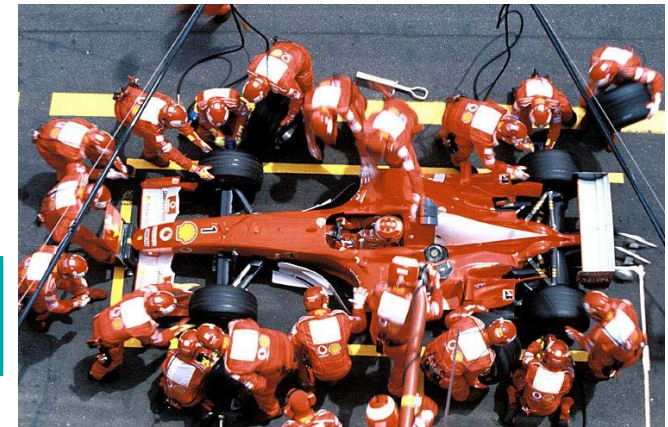
From: Charles Murray, 2003, *Human Accomplishment: The Pursuit of Excellence in the Arts and Sciences*
Additional reading: Lars Tvede, 2014 "the Creative Society", Yuval Noah Harari, 2014, "Sapiens" 9

Do EU provide the regulatory environment for encouraging innovation ??



Cowboys and Pit crews*

The Project Culture:



Could the Health Care system be organized in a Matrix centered around the patient and with a defined Project leader



* A. Gawande, *the New Yorker*, 2011
11

The Vision



From population



to individual



From biological
knowledge we can
provide individual risk
maps



We see a population of
similar individuals

We see a population of
different individuals



Why Health Care ?



Who is paying and is incentives aligned ?

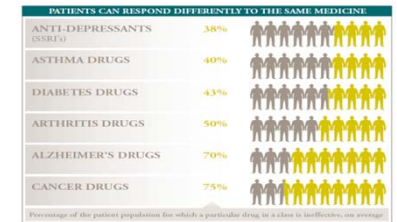


■ Payor 1 ■ Payor 2 ■ Employer ■ Payor 3



Where to apply a Personal Medicine approach

- Apply on existing medicines – segmentation into responders vs non-responders
- Apply in the process of new medicines development
- Apply in prevention – built on individual risk maps to provide guidance on healthy life



Science is leading to a revolution in healthcare:

- **The conventional “notion” of diseases will break-down**
Disease will be molecular “fault” defined and be an ‘orphan disease’
- **The molecular “fault” directs treatment**
Diseases with similar molecular ‘faults’ will have common therapies
- **Therapies will target a smaller group of individuals**
Diagnostic tests will determine who is ‘right’ and thus will benefit from the new treatment
- **Testing/valuation of new treatments requires better use of data**
Capturing data from the ‘real world’



Regulatory and reimbursement pathways must adapt to patient demands and scientific progress

- Proposed clinical trials regime does not adapt well to the smaller, targeted populations of personalized medicines
- Current pathways do not harness all of the tools at their disposal for better, more accurate, evaluation – i.e. statistical simulations, use of publically available data, patient driven and informed reward/risk assessment
- Innovative new drugs approved for sale in Europe are not being given reimbursement by national authorities, denying patients access to needed new treatments
- Current evaluation systems often do not measure the efficiency gaining impacts of new therapies nor accurately reflect their total net benefit



Barriers needs to be removed and incentives aligned

- ***To promote Innovations in personalized medicine we need to:***
- Invest in e-health records, biobanks, genetic databases and linking these up... 'real world' data should be harnessed to improve patient outcomes
- Create innovative evaluation systems and coherent HTA processes and flexible pricing are essential to better address the needs of patients and support access to personalised medicines
- Be able to document the economical benefits of individual health monitoring and availability of individual risk profiles combined with intervention strategies.



Conclusions and my predictions

- A Personalized or individualized approach to health care will be the core of a future Health Care system
- The future Health Care system will be a true health care system and not only a disease care system
- This transformation will require a number of issues to be addressed – this can ONLY be done as a collaboration between relevant parties



Thanks for your attention



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