

Panel Discussion: Can linked pharmacometric-health economic evidence improve (early) evaluation of new medicines?

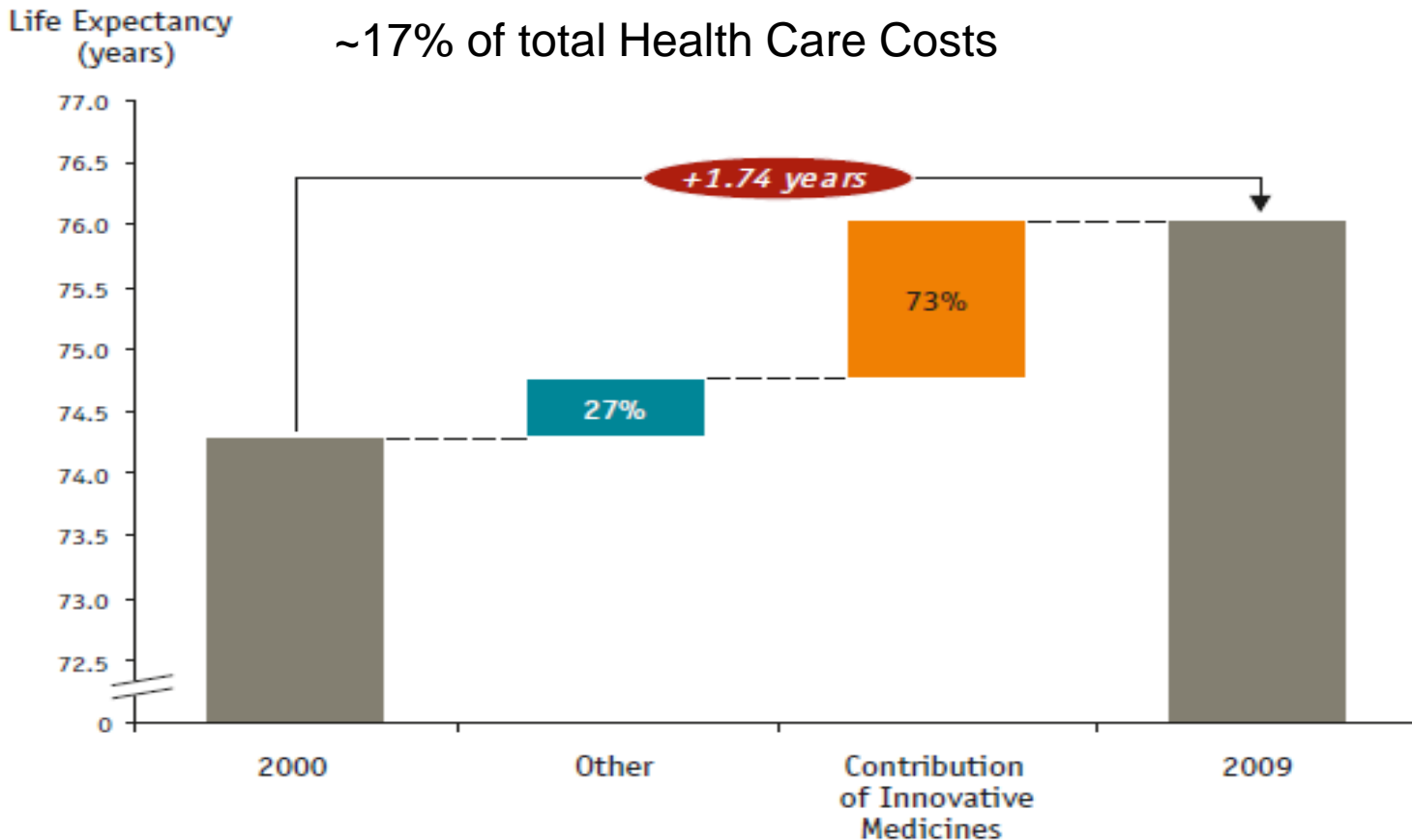
Scott Marshall PhD
Pharmacometrics
Global Clinical Pharmacology
Global Product Development
Pfizer Ltd Sandwich UK



GLOBAL PRODUCT DEVELOPMENT

There is no doubt that Innovative medicines make a difference to our lives

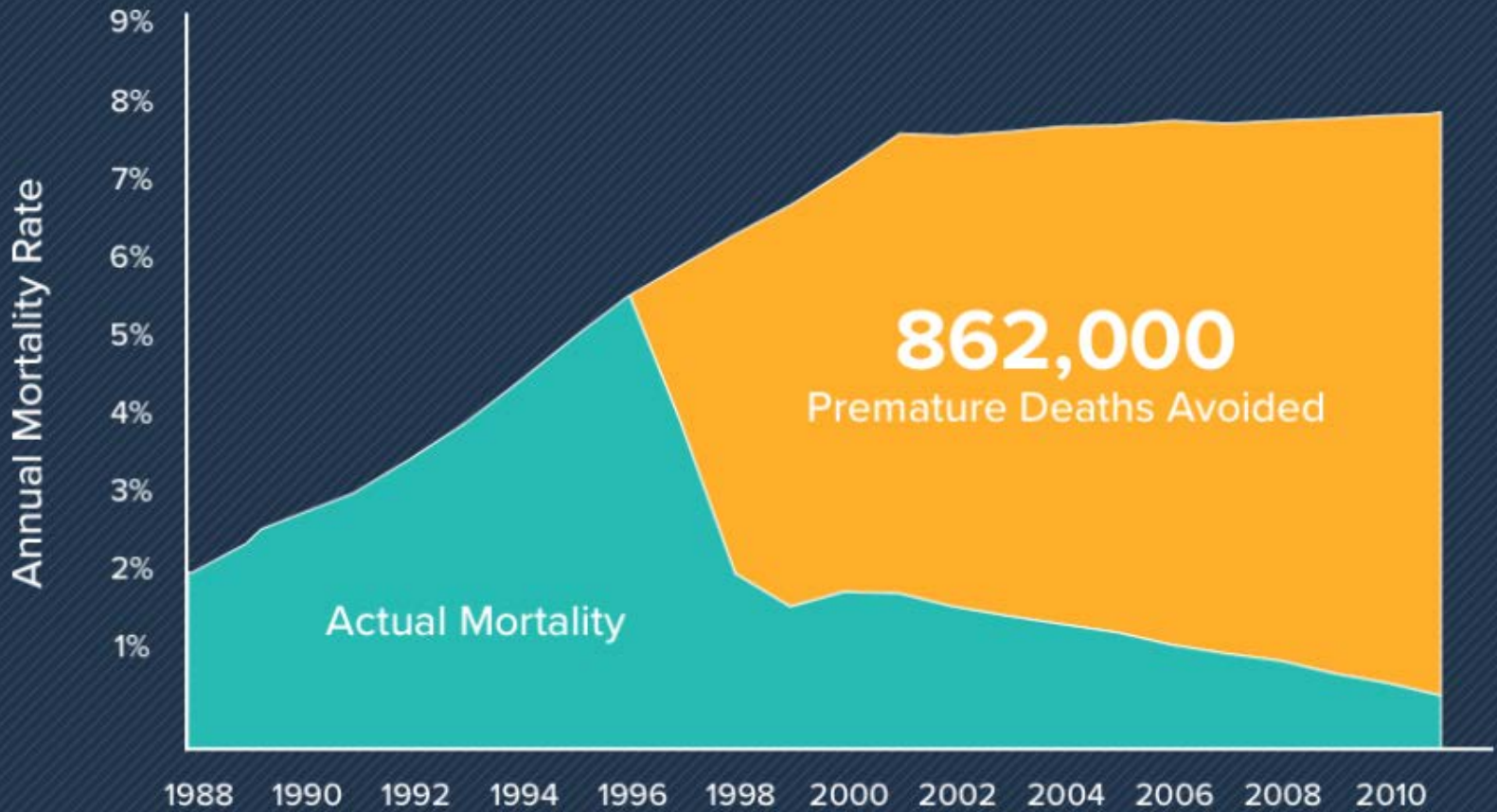
CONTRIBUTION OF INNOVATIVE MEDICINES TO INCREASE IN LIFE EXPECTANCY (2000-2009)



Source: Lichtenberg, F: Pharmaceutical innovation and longevity growth in 30 developing OECD and high-income countries, 2000-2009 (2012)

For Example...

ACTUAL VS PROJECTED DEATH RATES FOR HIV/AIDS IN THE UNITED STATES



However, there is a view that industry charges too much :

THE DRUG COST DEBATE AT A GLANCE



**\$457
BILLION**

The amount
Americans spent
on prescription
drugs in 2015,
up by about 8
percent over the
previous year

208%

The rise in prices
for the most
popular brand-
name drugs from
2008 to 2016

**\$14.5
MILLION**

Median salary of
a pharmaceutical
firm CEO in 2015,
more than any
other industry

**\$6.4
BILLION**

Amount drug
companies
spend advertising
directly to
consumers in the
U.S. annually

**\$24
BILLION**

Amount drug
companies
spend per year
marketing to
doctors

AMY SHROADS

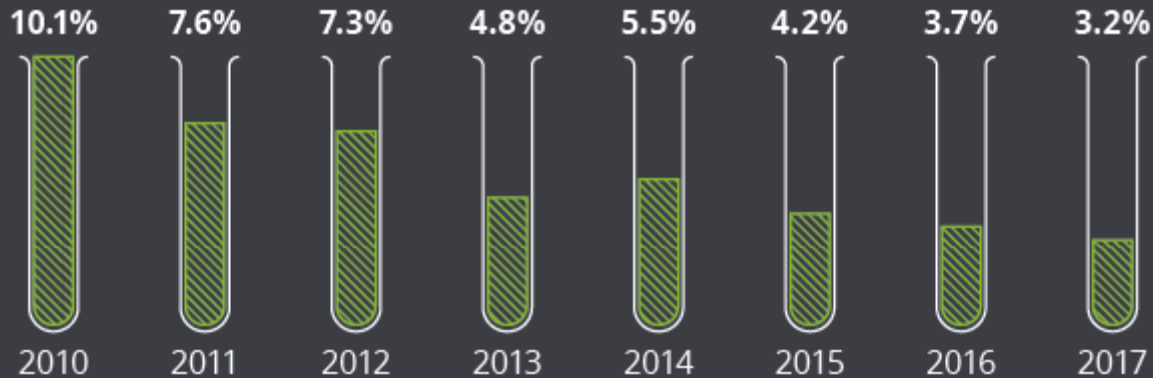
<https://www.aarp.org/health/drugs-supplements/info-2017/rx-prescription-drug-pricing.html>



GLOBAL PRODUCT DEVELOPMENT

But ROI is declining

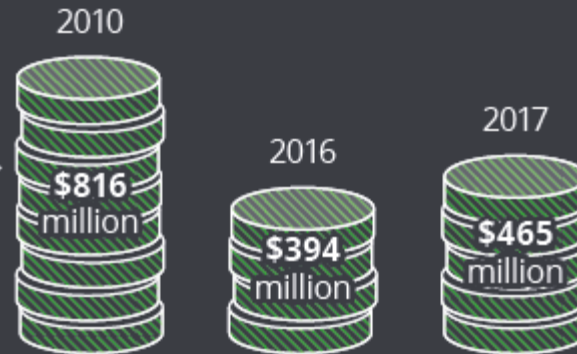
For the original large cap biopharma cohort:
Projected R&D returns continue to decline



Cost to **bring an asset to market** has increased to record levels in 2017

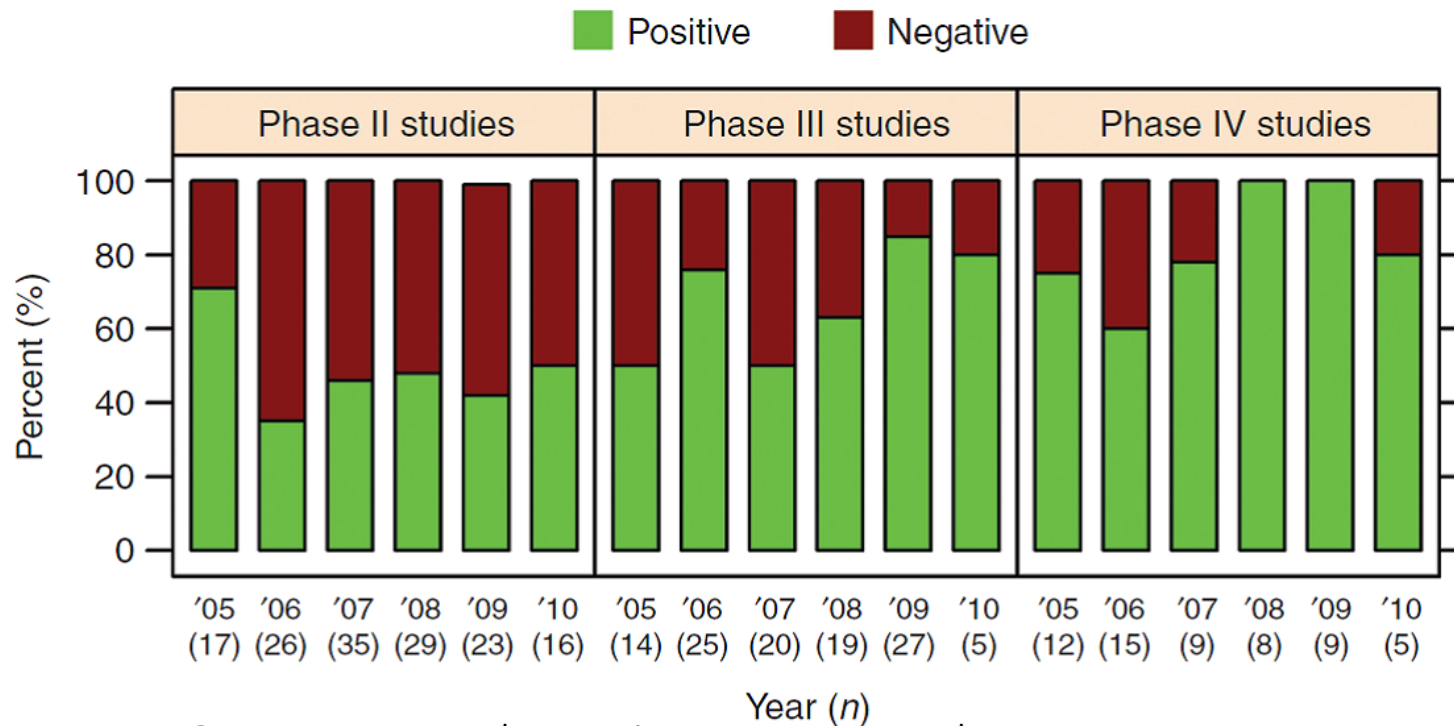


Projected peak sales per asset **more than halved** between 2010 and 2016 but have increased by 18% in 2017



<https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/measuring-return-from-pharmaceutical-innovation.html>

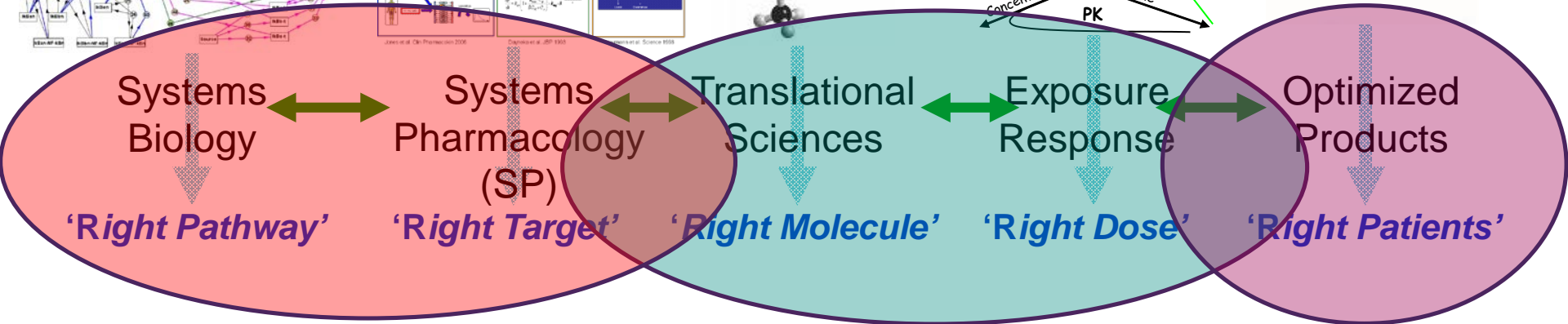
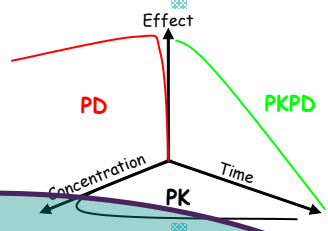
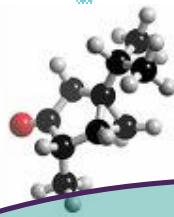
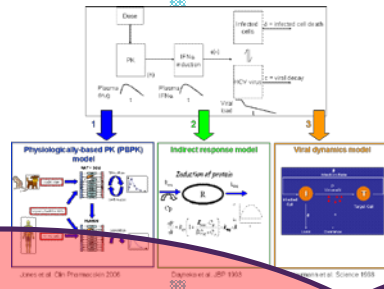
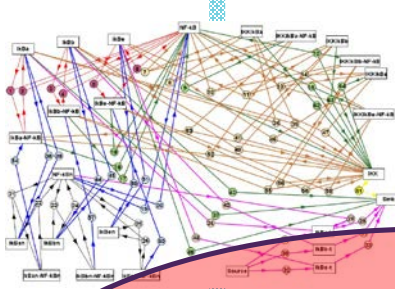
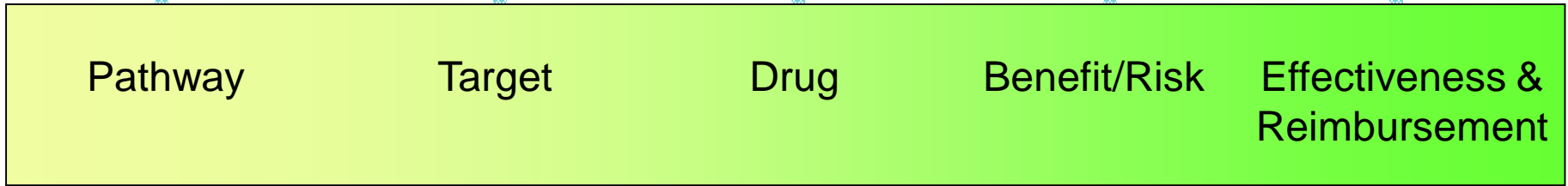
However, we have seen the impact on Cost & Value from industrial application of Pharmacometrics...



Year (n)
 Saving 2005 \$70m / 2007 budget -\$100m

Figure 2 Phase II, III, and IV study outcomes (% positive or negative for the primary efficacy outcome) following MBDD implementation. The year refers to when each specific study was initiated. The number in parenthesis provides the actual number of studies to subsequently complete and form the basis of the reported percentages. MBDD, model-based drug development.

One solution to increasing R&D Efficiency : Predictions from Pathway to Payer & Back



Panel Discussion: Questions to the Presenters

- Is Network Meta-analysis and Model based Meta-analysis two sides of the same coin?
- Can we define where using Pharmacometrics approaches is essential in appropriately evaluating cost effectiveness at any stage in drug development?
- How do DICE simulations deal with more dynamic situations e.g. changing in adherence, resulting in an integration of treatment effect and therefore probability of an outcome over time?
- If you were to assume the position of an “end user” (Decision maker, Payer, patient), how convinced would you be that the integration of these disciplines is a key component to improving R&D efficiency?
- In general what can Pharmacometric and Pharmacoeconomic analysts learn from each other?

Panel Discussion: Pathway to Payer and back

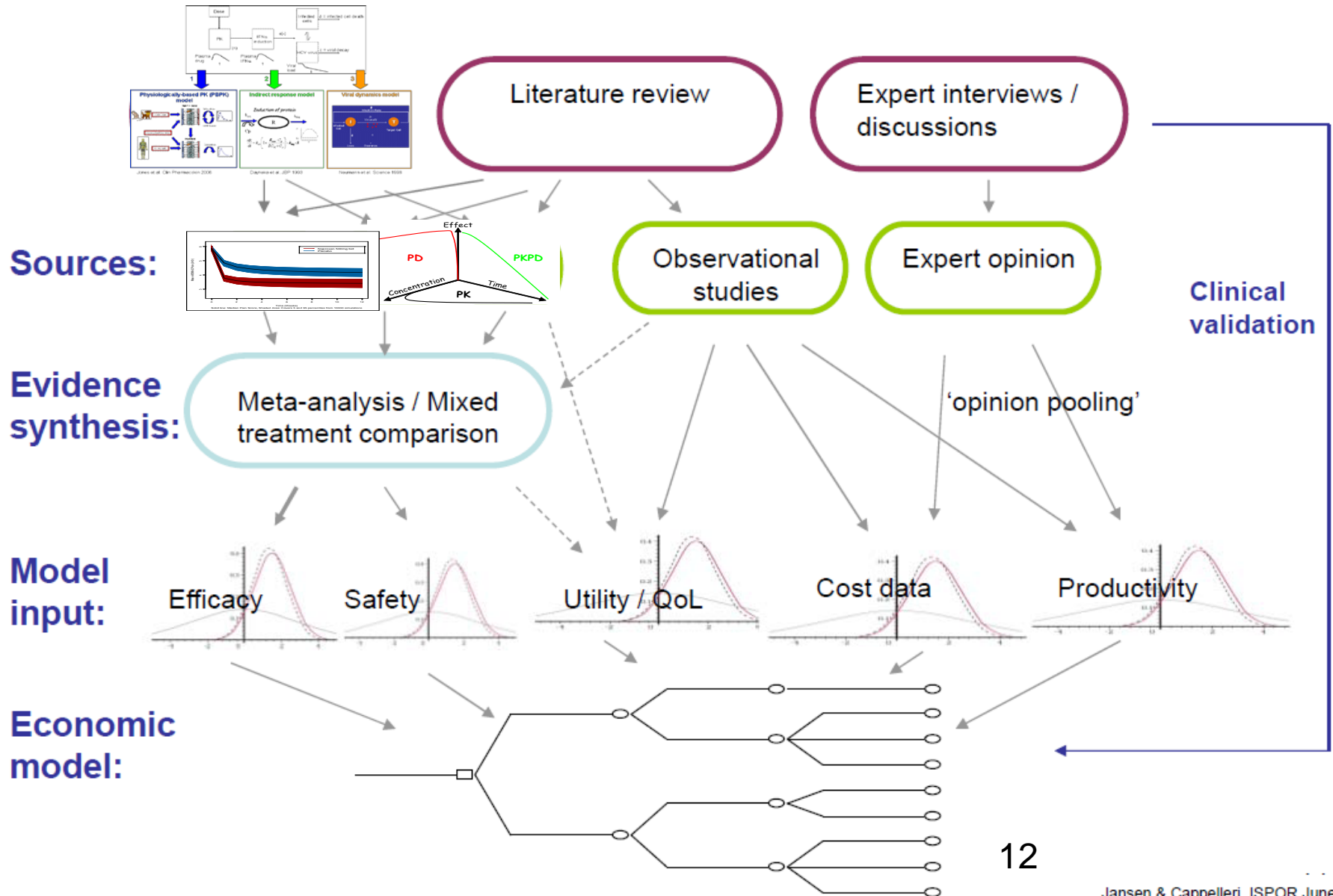
- Pathway to Payer Application
 - What examples \ evidence do we have of the benefit of using pharmacometrics to make **early cost effectiveness evaluations**?
 - Or where do you think it would be most valuable?
 - How should we manage the uncertainty in the extrapolations in helping to make what are essentially clinical based decisions?
- Payer to Pathway Application
 - To what extent should we lead **our product concepts and our future R&D strategy** by where we predict we have a cost effective medicine?
 - How easily can we factor in the emerging competitive landscape into this prediction?

Panel Discussion: Improving PMx CE Linkage

- How do we advance our knowledge of each others disciplines?
- Is there a need for a taxonomy that brings together standard terminology used across the disciplines?
- How do we remove organizational barriers and create collaborations across disciplines?
- How close are we in respect of using common tools and standards in processes such as evidence synthesis? and is this an impediment?
- How easily would Payers be able to accept and evaluate “Pharmacology, Physiology and Pathology based models” as inputs into cost effectiveness analysis and what can we do to influence this situation?
- When we think globally, how varied would payers be across different countries/regions in this respect?

Back-ups

Pathway to Payer: Early Decisions



Payer to Pathway : Concepts & Plan

