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

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Pharmacometrics
Global Clinical Pharmacology
Global Product Development
Pfizer Ltd  Sandwich UK
There is no doubt that Innovative medicines make a difference to our lifes

~17% of total Health Care Costs

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

For Example…

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

862,000
Premature Deaths Avoided

http://phrma.org/industryprofile/
However, there is a view that industry charges too much:

But ROI is declining ....

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.

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

2010 10.1%
2011 7.6%
2012 7.3%
2013 4.8%
2014 5.5%
2015 4.2%
2016 3.7%
2017 3.2%

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

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

Pathway → Target → Drug → Benefit/Risk → Effectiveness & Reimbursement

Systems Biology
‘Right Pathway’

Systems Pharmacology (SP)
‘Right Target’

Translational Sciences
‘Right Molecule’

Exposure Response
‘Right Dose’

Optimized Products
‘Right Patients’

Systems Models

Pharmacometrics Models

CE Models
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 other's 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

#### Sources:
- Literature review
- Expert interviews / discussions
- Observational studies
- Expert opinion

#### Evidence synthesis:
- Meta-analysis / Mixed treatment comparison

#### Model input:
- Efficacy
- Safety
- Utility / QoL
- Cost data
- Productivity

#### Economic model:

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### Table

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*Jansen & Cappelleri, ISPOR June 2012*
Payer to Pathway: Concepts & Plan

- Sources:
  - Literature review
  - Expert interviews/discussions
  - Observational studies
  - Expert opinion

Quantitative Product Concept (TV)

Model input:
- Efficacy
- Safety
- Utility/QoL
- Cost data
- Productivity

Economic model:

\[ \begin{align*}
\text{PD} & \quad \text{PK} \\
\text{PKPD} & \quad \text{Time} \\
\text{Mean WOMAC Pain (0-10)} & \\
0 & 2 & 4 & 6 & 8 & 10 & 12 \\
3 & 4 & 5 & 6
\end{align*} \]

Naproxen 500mg bid

- Placebo