


Moderator

Second Plenary Session
 The Reality of Real World Data and its Use in Health Care Decisions in Europe



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Speakers

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 The Reality of Real World Data and its Use in Health Care Decisions in Europe





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 Vice President
 Payer Evidence
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Second Plenary Session at ISPOR 14th Annual European Congress

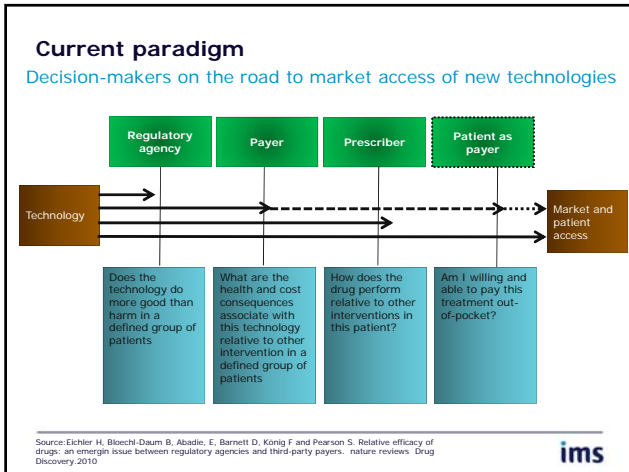
The reality of real world data and its use in health care decisions in Europe

7th November 2011

Setting the Scene of Today's Plenary

- Initial decisions on reimbursement of a new technology usually include the extent to which it does more good than harm under ideal circumstances [efficacy].
- How is this information on 'usual circumstance of health care practices' being collected, analyzed, and reported?
- Who is responsible for collecting, analyzing and reporting the information? Manufacturers? Government?
- During this session, the issues of collecting and analyzing real world data, such as observational studies will be link to health decision making examples





- ### Comparative Efficacy
- The comparative active efficacy has been largely requested by many institutional and academic bodies at regulatory level
 - Manufacturers has focused on comparative efficacy to meet risk-benefit ratio
 - Payers focus on CE to optimize health outcomes of population while accounting for a budgetary constraint
 - Industry and regulatory bodies such as EMA should change to meet payer requirements?
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Efficacy and Effectiveness

- Efficacy is the extent to which an intervention does more good than harm under ideal circumstances of health care practice.
- Effectiveness is the extent to which an intervention does more than harm under the usual circumstances of health care practice

Efficacy \neq Effectiveness

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Effecacy (Effectiveness + Efficacy)

What is effecacy?

- Effecacy is when looking at the efficacy (health benefits) of the new drug compared with the current existing options, we compare efficacy data of the new one with efficacy and effectiveness data of the current options (**relative effecacy**).
- Effecacy is used by payers to extrapolate results such as RCT into real life in their decision making process about the value of the new technology compared to get reimbursement

Effecacy

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After Efficacy?, Comparative Effectiveness Research (CER)

- Comparative effectiveness research is the generation and synthesis of evidence that compares the benefits and harms to prevent, diagnose, treat and monitor a clinical condition.



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Agenda

- 8:35-8:42 Introduction: The reality of world data and its use in healthcare decisions
Xavier Badia, IMS Consulting Group
- 8:42-8:59 The reality of world data and its use in Health Care decisions
Leslie Levin, Medical Advisory Secretariat Ontario
- 8:59-9:16 The reality of world evidence: An industry point of view
Patrick Keohane, AstraZeneca
- 9:16-9:33 The Healthcare Quality of the Spanish SNS under scrutiny
Enrique Bernal, Health Services Research and Health Policy Unit
- 9:33-9:45 Q&A

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