IMI-PROTECT AND BENEFIT-RISK
Ed Waddingham, Imperial College London

Facts & Figures
Start date: 01/09/2009
End date: 01/03/2015
Contributions
IMI funding: 11 009 715 €
EFPIA in kind: 10 864 491 €
Other: 6 743 176 €
Total Cost: 28 617 382 €
Project website: www.imi-protect.eu
Social media: twitter/protect_br

MCDA with Bayesian network meta-analysis demonstrating comparison of benefit-risk score (a composite measure reflecting performance in relation to several clinical outcomes) for multiple sclerosis treatments, allowing for statistical uncertainty of the original outcome measures

Results

MCDA with Bayesian network meta-analysis

Evidence network Distribution of benefit-risk score

Network meta-analysis combines head-to-head trials to give estimates of the indirect comparisons

Decision

Decision process needs sound principles & clarity of reasoning

Approach & Methodology

The presenter:
• developed as his MSc project a Bayesian extension of multi-criteria decision analysis (MCDA), a method to help with treatment decisions under conflicting objectives (i.e. maximising benefit and minimising risks)
• took the lead in writing the team’s recommendations on benefit-risk integration

Challenge

PROTECT aimed to examine methods for monitoring drug safety and evaluating the overall balance of benefits and risks, covering four broad areas as shown. The presenter was involved in the benefit-risk integration work package.

From the point when marketing authorisation is sought for a drug, authorities need to weigh up its clinical benefits and risks to determine whether it is fit for general use. There were concerns that the process of gathering and combining evidence was often too informal and could be improved.

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