10 YEARS OF BREAKTHROUGHS A HEALTHIER FUTURE

PROTECT

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IMI-PROTECT AND BENEFIT-RISK

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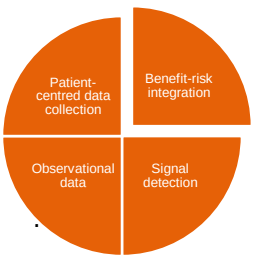
Facts & Figures

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

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.

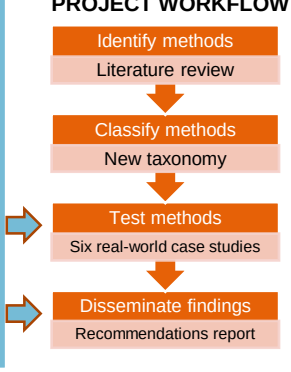
Decision process needs sound principles & clarity of reasoning

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

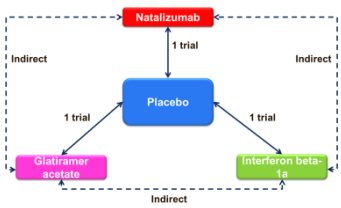
PROJECT WORKFLOW



Results

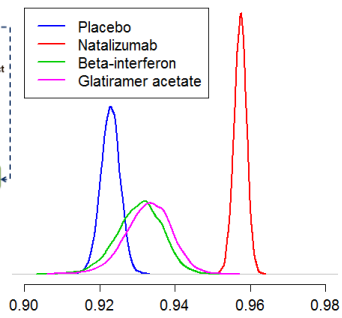
MCDA with Bayesian network meta-analysis demonstrating comparison of benefit-risk score (a composite measure reflecting performance in relation to several clinical outcomes) for multiple sclerosis treatments, allowing for statistical uncertainty of the original outcome measures

Evidence network



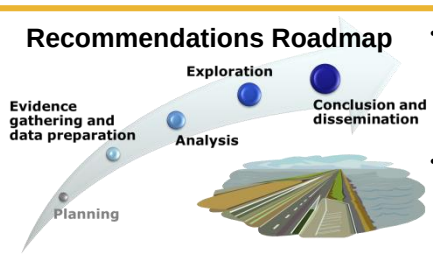
Network meta-analysis combines head-to-head trials to give estimates of the indirect comparisons

Distribution of benefit-risk score



Transparent process from evidence to final conclusion

Recommendations Roadmap

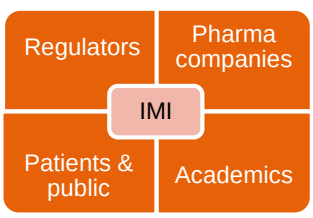


- Set of recommendations on assessing benefit-risk balance
- Now incorporated into regulatory guidance

+ many more results from our work package
+ even more from the rest of PROTECT

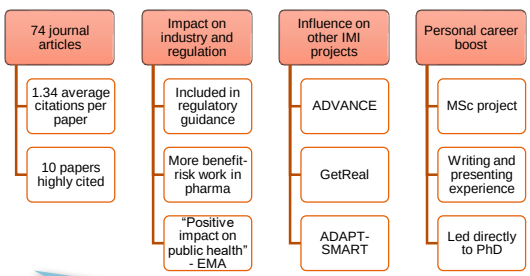
Value of IMI collaboration

All key stakeholders represented in consortium:



- Ensured quality and relevance of research
- Helped our message get to the right people
- Great way for this young researcher to learn about the industry

Impact & take home message



In conclusion: PROTECT has increased awareness, understanding and adoption of methods that can improve the **quality, transparency and timeliness** of regulatory decisions, improving **public confidence** and potentially **reducing delays in drug licensing.**

imi innovative medicines initiative efpia

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