PROTECT

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Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium

VISUALISING BENEFITS AND RISKS: CONCEPTS AND IDEAS

IMI-PROTECT Symposium

Benefit-Risk Integration and Representation Workshop

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Disclaimer

"The processes described and conclusions drawn from the work presented herein relate solely to the testing of methodologies and representations for the evaluation of benefit and risk of medicines.

This report neither replaces nor is intended to replace or comment on any regulatory decisions made by national regulatory agencies, nor the European Medicines Agency."

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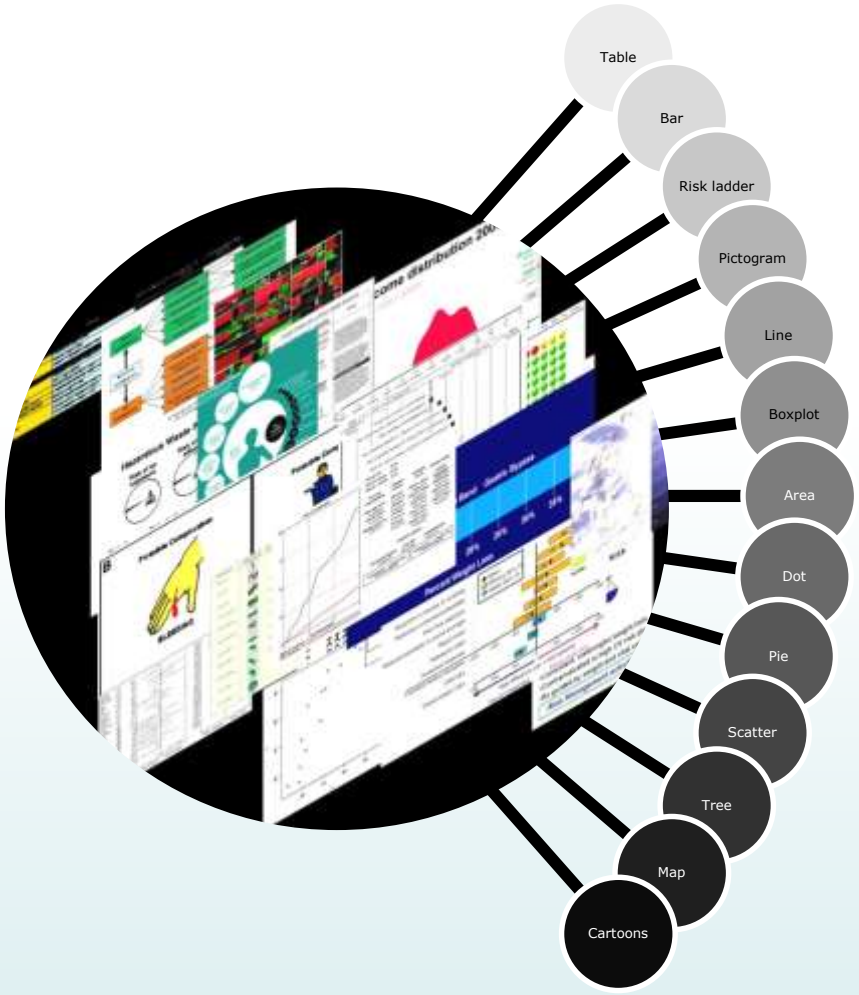
Many research on visualisations

Lack of use in formal B-R assessment

Graphics and other formats




Verbal Labels Can Triple Perceived Risk in Clinical Trials

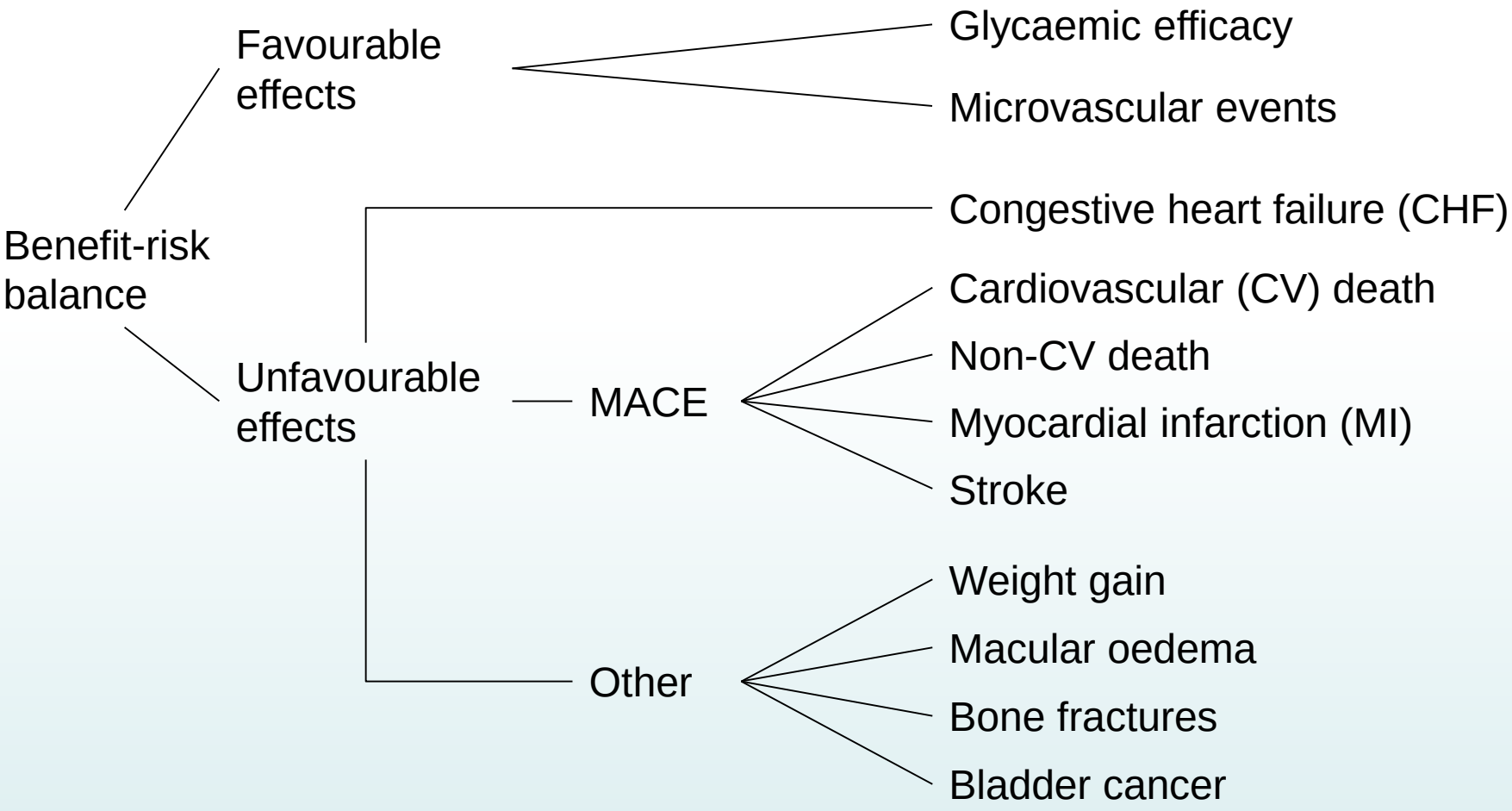
The purpose of this study was to assess whether the use of verbal descriptors, such as "common" and "rare" affects people's perceptions of the risks involved in clinical trials as well as their likelihood of entering into the trial. Participants were required to imagine that they had a serious skin condition and being asked if they would take part in a clinical trial for a new drug. They

bal labels alone or verbal labels with associated numerical values. The results showed that those given just the verbal descriptors were significantly less satisfied with the information, perceived risk to be higher (by a factor of three) and benefit to health to be lower, and indicated that they would be significantly less likely to enter the trial. We recommend that patients are informed

http://intl-dij.sagepub.com/content/40/3/249.refs

		Treatment A	Treatment B
Benefits (higher is better)	Physician's view on **HDL Cholesterol levels**	Mild improvement	No change
	Number of people who experience a **10% weight loss**	10 out of 1000	450 out of 1000
Risks (lower is better)	Number of people who experience **psychiatric conditions**	100 out of 1000	1 out of 1000
	Number of people who experience **cardiovascular conditions**	1 out of 1000	100 out of 1000
	Number of people who experience **gastrointestinal conditions**	1 out of 1000	None

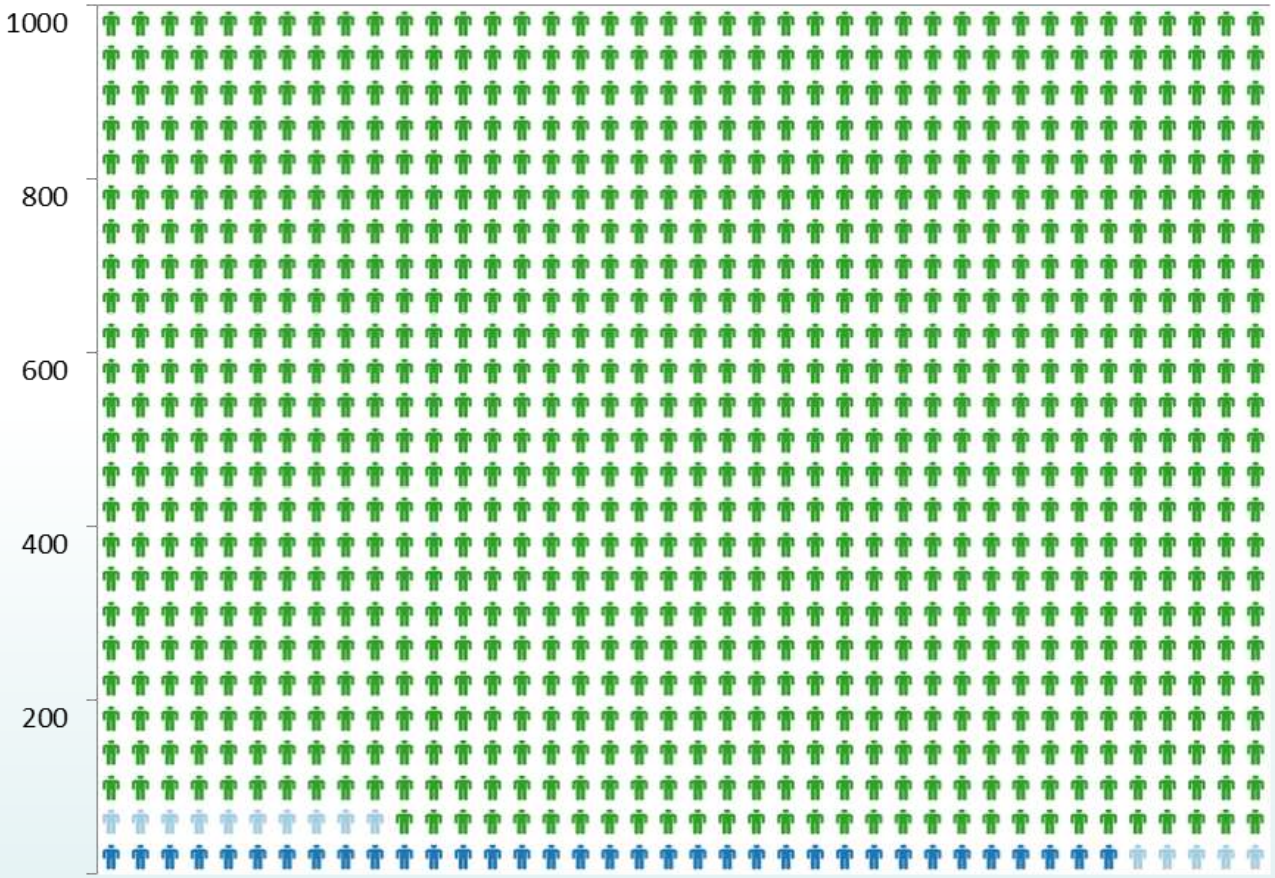
Tree diagram – a value tree



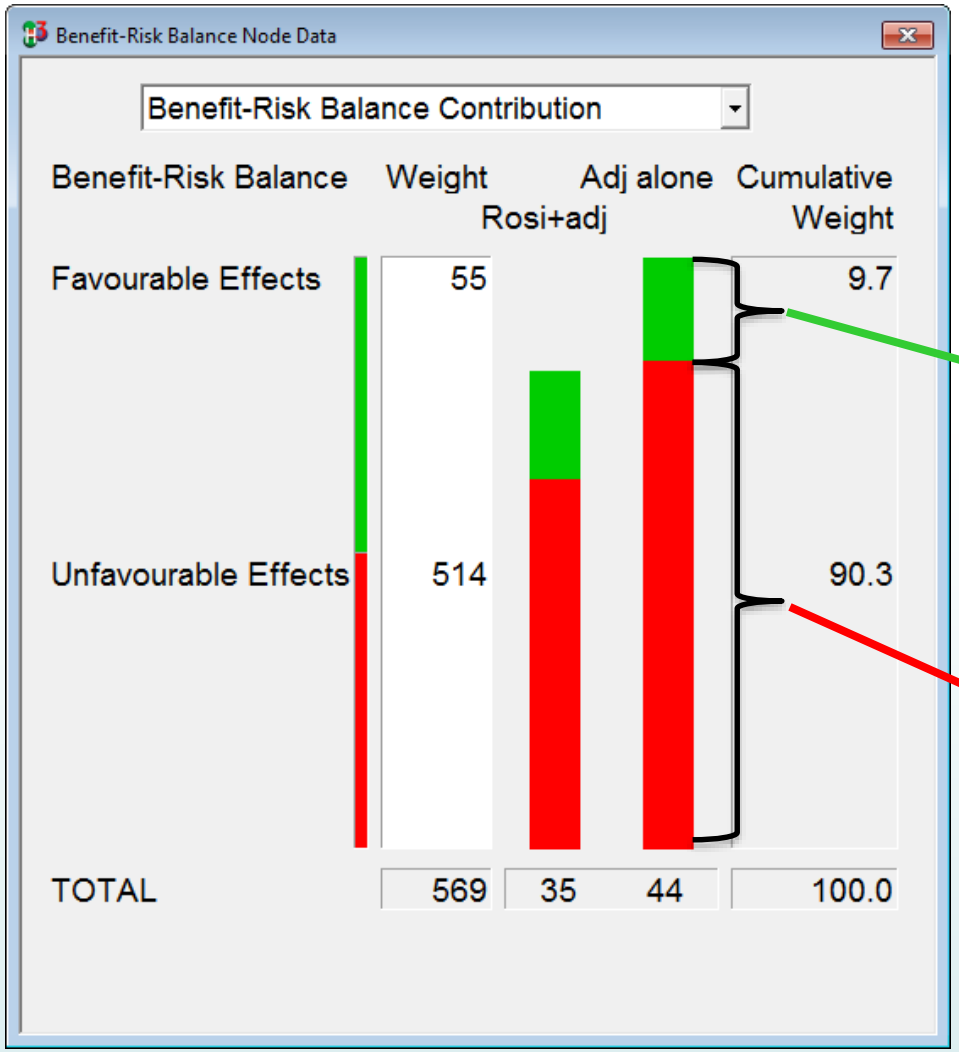
Effects table

		Name	Description	Fixed Upper	Fixed Lower	Unit	Rosi + adjunct	Adjunct only
Favourable effects		Glycaemic efficacy	(A surrogate marker of the quality of glucose regulation.) Mean change from baseline in the proportion of Hb in which A1c is greater than 48 mmol/ml.	5.00	-5.00	%	-1.18	0.06
		Micro-vascular events	Incidence of new cases of microvascular events compared to baseline (Retinopathy requiring photocoagulation, vitreous haemorrhage, & fatal or non-fatal renal failure.)	20.00	0.00	%	2.70	3.50
Unfavourable Effects		CHF	Proportion of patients experiencing congestive heart failure during the study period.	4.00	0.00	%	3.69	1.89
	MACE	CV death	The proportion of patients who died from any cardiovascular event including stroke.	4.00	0.00	%	2.70	3.19
		Non-CV death	The proportion of patients who died from any non-cardiovascular event including stroke.	4.00	0.00	%	2.97	3.86
		MI	Proportion of patients who experience a non-fatal heart attack.	5.00	0.00	%	3.33	3.01
		Stroke	Proportion of patients who experience a non-fatal ischemia stroke.	5.00	0.00	%	1.94	2.83
	Other	Weight gain	Mean change from baseline in weight gain at 1 yr.	10.00	-5.00	Kg	3.80	0
		Macular oedema	Proportion of patients who experience macular oedema.	1.00	0.00	%	1.27	0.23
		Bone fractures	Proportion of patients experiencing bone fractures.	3	0	%	8.33	5.3
		Bladder cancer	Proportion of patients contracting bladder cancer.	1.00	0.00	%	0.27	0.22

Pictogram


1000
800
600
400
200
Patients who will die from any-cause over a course of one year whether they take warfarin or not
Patients who will be saved from dying by any-cause over a course of 1 year by taking warfarin
Patients who will not die from any-cause over a course of one year whether they take warfarin or not

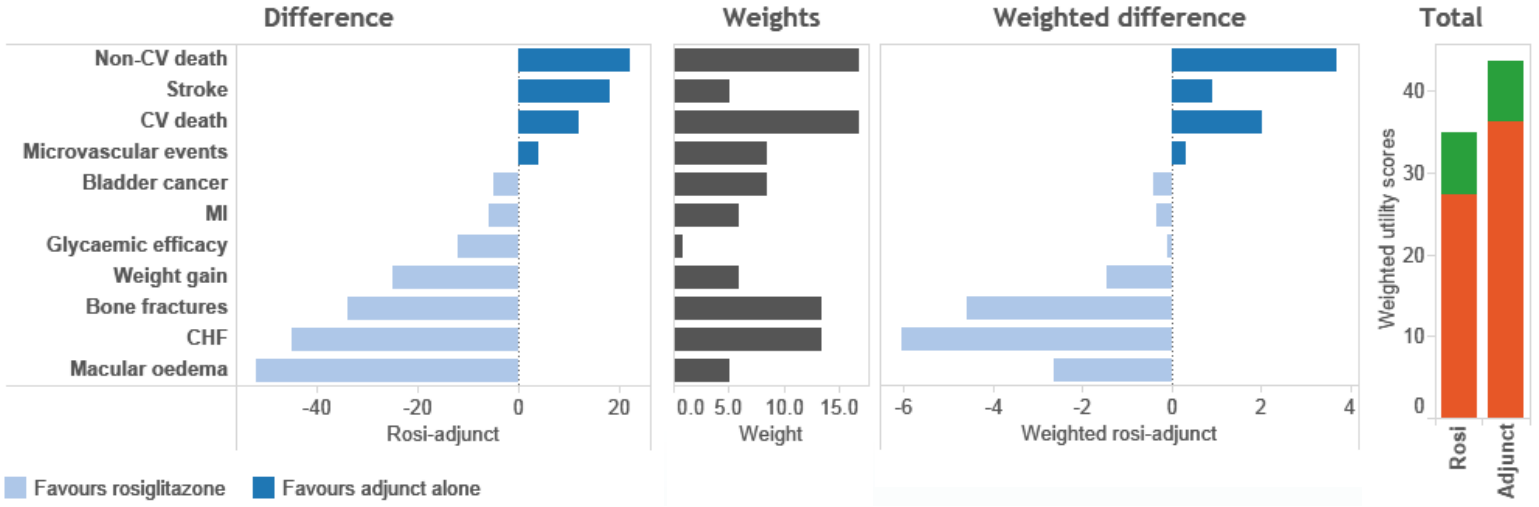
Stacked bar graph



More green, more benefit

More red, more safe

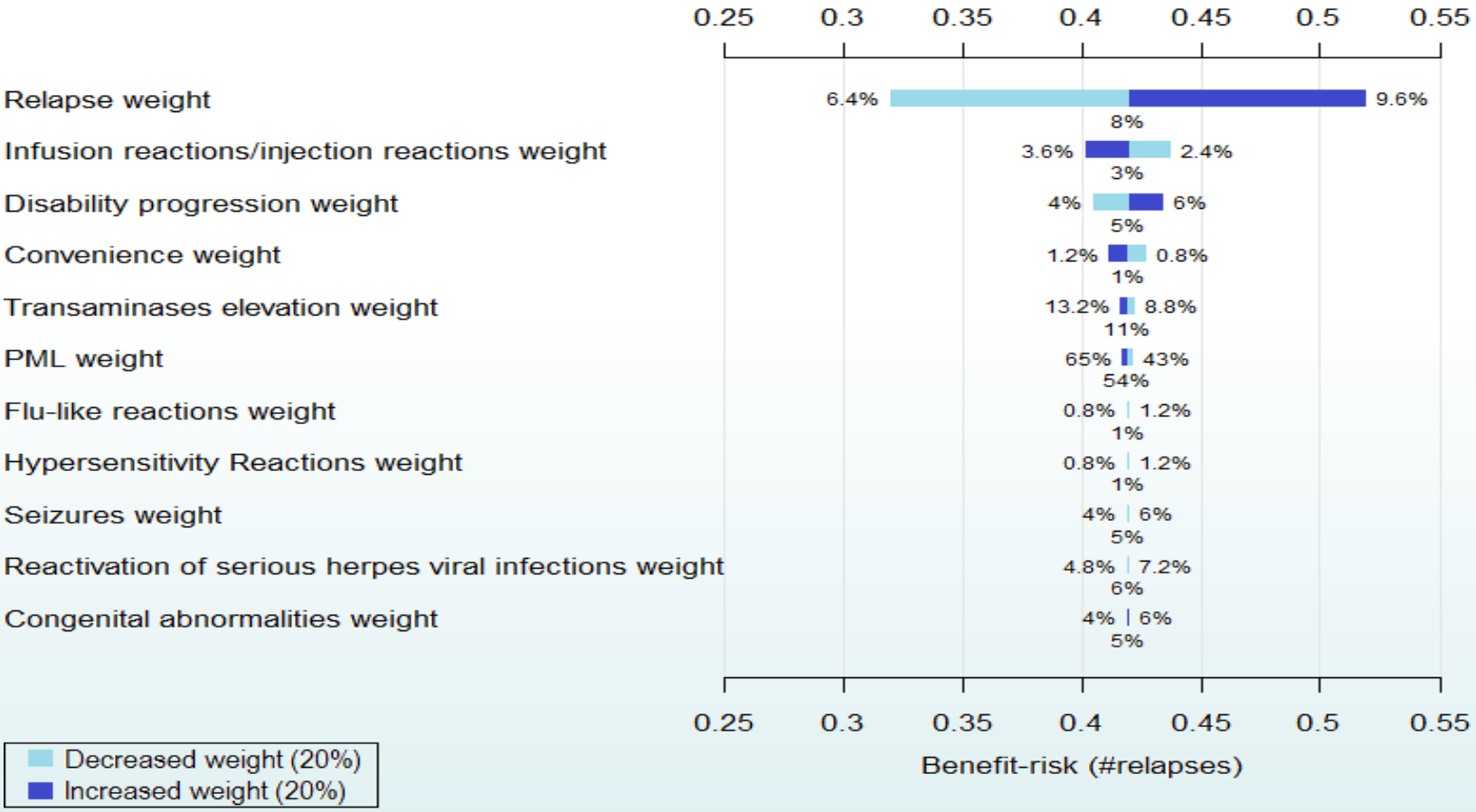
Interactive visual display



Drag sliders to assign weights on criteria

Non-CV death: 50	
CV death: 50	Bladder cancer: 25
Stroke: 15	Weight gain: 17.5
Microvascular events: 25	Macular oedema: 15
Glycaemic efficacy: 2.5	Bone fractures: 40
Myocardial infarction: 17.5	CHF: 40

Tornado-diagram



Remarks on visual representation

- No one visual type fits all
- Different visual types carry information differently
- Different user may prefer different visual representation – cannot always generalise
  - Visual type preference study shows preference towards tables and bar graphs
  - Understanding and/or preferences may still be affected by the actual information being displayed
- Visual representation formats should be tested with the intended audience before actual use

ACKNOWLEDGEMENT

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- The research leading to these results was conducted as part of the PROTECT consortium (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium, www.imi-protect.eu) which is a public-private partnership coordinated by the European Medicines Agency.

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