



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Clinical trial data and B/R assessment of medicines

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What is required from a regulatory agency?

"A fair regulatory process requires accountability for reasonableness, i.e., publicity about the reasons and rationales that play a part in decisions"

(Daniels N, Accountability for reasonableness, BMJ, 2000)



Benefit/Risk



Clinical trial data on efficacy and safety

Attribute	Description	Drug X	Placebo
Favourable effects			
1-year PFS	Percentage of patients being alive and progression-free for 1 year or longer	80% (71%, 87%)	65% (55%, 74%)
Unfavourable effects			
Severe adverse event risk	Risk of experiencing an adverse event that could result in long-term or permanent disability	25% (18%, 34%)	5% (2%, 11%)
Chronic moderate toxicity risk	Risk of experiencing recurrent episodes during which the treatment causes you to feel unwell	55% (45%, 64%)	30% (22%, 40%)

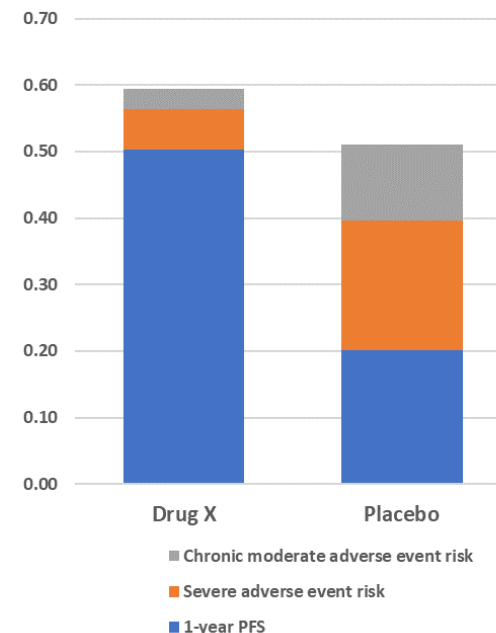


Value judgement

Effect	Max Acc Risk	Worst	Best	Importance
1-year PFS	10%	55%	87%	100%
Severe adverse event risk	30%	2%	30%	33%
Chronic moderate toxicity risk	60%	22%	60%	22%



Value profile





Thank you for your attention

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