

ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

Form 2a: For therapies that are not likely to be curative with primary endpoint of OS

Name of study:			
Study medicine:		Indication:	
First author:		Year:	Journal:
Name of evaluator:			

IF median OS with the standard treatment is ≤ 1 year

Grade 4

	Mark with \checkmark if relevant
HR ≤ 0.65 <u>AND</u> gain ≥ 3 months	
Increase in 2-year survival alone $\geq 10\%$	

Grade 3

HR ≤ 0.65 <u>AND</u> gain 2.5 - 2.9 months	
Increase in 2-year survival alone 5 - $<10\%$	

Grade 2

HR $>0.65 - 0.70$ <u>AND</u> gain 1.5 - 2.4 months	
Increase in 2-year survival alone 3 - $<5\%$	

Grade 1

HR >0.70 <u>OR</u> gain <1.5 months	
Increase in 2-year survival alone $<3\%$	

Preliminary magnitude of clinical benefit grade (highest grade scored)

4	3	2	1

Quality of Life/Grade 3-4 toxicities* assessment

Does secondary endpoint QoL show improvement?	
Are there statistically significantly less grade 3-4 toxicities impacting on daily well-being*?	

*This does not include alopecia, myelosuppression, but rather chronic nausea, diarrhoea, fatigue, etc.

Adjustments

Upgrade 1 level if improved QoL and/or less grade 3-4 toxicities impacting daily well-being are shown

Final adjusted magnitude of clinical benefit grade

5	4	3	2	1