

ESMO Magnitude of Clinical Benefit Scale v1.1

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

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

IF median OS with the standard treatment is ≤ 12 months

	Mark with X if relevant
Grade 4	
HR ≤ 0.65 <u>AND</u> Gain ≥ 3 months	
Increase in 2 year survival $\geq 10\%$	

Grade 3

HR ≤ 0.65 <u>AND</u> Gain ≥ 2.0 , < 3 months	
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Grade 2

HR ≤ 0.65 <u>AND</u> Gain ≥ 1.5 , < 2.0 months	
HR $> 0.65-0.70$ <u>AND</u> Gain ≥ 1.5 months	

Grade 1

HR > 0.70 <u>OR</u> Gain < 1.5 months	
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Preliminary magnitude of clinical benefit grade (highest grade scored)

4	3	2	1

Quality of Life assessment /grade 3-4 toxicities assessment*

Does secondary endpoint quality of life 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

1. Upgrade 1 level if improved quality of life and/or less grade 3-4 toxicities impacting daily well-being are shown
2. If there is a long-term plateau in the survival curve, and OS advantage continues to be observed at 5 year, also score according to form 1 (treatments with curative potential) and present both scores i.e. A/4

Final adjusted magnitude of clinical benefit grade

5	4	3	2	1