

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 >12 months ≤24 months

	Mark with X if relevant
Grade 4	
HR ≤0.70 <u>AND</u> Gain ≥5 months	
Increase <u>in</u> 3 year survival alone ≥10%	

Grade 3

HR ≤0.70 <u>AND</u> Gain ≥3-<5 months	
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Grade 2

HR ≤0.70 <u>AND</u> Gain ≥1.5-<3 months	
HR >0.70-0.75 <u>AND</u> Gain ≥1.5 months	

Grade 1

HR > 0.75 <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 7 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