

## 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 >24 months

	Mark with X if relevant
<b>Grade 4</b>	
HR $\leq 0.70$ <u>AND</u> Gain $\geq 9$ months	
Increase <u>in</u> 5 year survival alone $\geq 10\%$	

**Grade 3**

HR $\leq 0.70$ <u>AND</u> Gain $\geq 6$ -<9 months	
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**Grade 2**

HR $\leq 0.70$ <u>AND</u> Gain $>4$ -<6 months	
HR $>0.70$ - $0.75$ <u>AND</u> Gain $\geq 4$ months	

**Grade 1**

HR $>0.75$ <u>OR</u> Gain <4 months	
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Preliminary magnitude of clinical benefit grade (highest grade scored)

<b>4</b>	<b>3</b>	<b>2</b>	<b>1</b>

**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**

<b>5</b>	<b>4</b>	<b>3</b>	<b>2</b>	<b>1</b>