



GOOD SCIENCE  
 BETTER MEDICINE  
 BEST PRACTICE

## 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 drug:	Indication:	
First author:	Year:	Journal:
Name of evaluator:		

**IF median OS with the standard treatment is  $\leq$  1 year**

	<i>Mark with X if relevant</i>
<b>Grade 4</b>	
HR $\leq$ 0.65 <u>AND</u> Gain $\geq$ 3 months	
Increase <u>in</u> 2 year survival alone $\geq$ 10%	
<b>Grade 3</b>	
HR $\leq$ 0.65 <u>AND</u> Gain 2.5-2.9 months	
Increase <u>in</u> 2 year survival alone 5 - <10%	
<b>Grade 2</b>	
HR > 0.65-0.70 <u>AND</u> Gain 1.5-2.4 months	
Increase <u>in</u> 2 year survival alone 3 - <5%	
<b>Grade 1</b>	
HR > 0.70 <u>OR</u> Gain <1.5 months	
Increase <u>in</u> 2 year survival alone <3%	

**IF median OS with the standard treatment is  $\leq$  1 year**

**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**

Upgrade 1 level if improved quality of life 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

**IF median OS with the standard treatment  $>$  1 year**

Grade 4	<i>Mark with X if relevant</i>
HR $\leq$ 0.70 <u>AND</u> Gain $\geq$ 5 months	
Increase <u>in</u> 3 year survival alone $\geq$ 10%	

### Grade 3

HR ≤ 0.70 <u>AND</u> Gain 3-4.9 months	
Increase <u>in</u> 3 year survival alone 5 - <10%	

### Grade 2

HR > 0.70-0.75 <u>AND</u> Gain 1.5-2.9 months	
Increase <u>in</u> 3 year survival alone 3 - <5%	

### Grade 1

HR > 0.75 <u>OR</u> Gain <1.5 months	
Increase <u>in</u> 3 year survival alone <3%	

### 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

Upgrade 1 level if improved quality of life 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