

ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE V1.1 EVALUATION 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 >12 months ≤24 months

GRADE 4	HR ≤0.70 <u>AND</u> gain ≥5 months	<input type="radio"/>
	Increase in 3 year survival alone ≥10%	<input type="radio"/>
GRADE 3	HR ≤0.70 <u>AND</u> gain ≥3-<5 months	<input type="radio"/>
GRADE 2	HR ≤0.70 <u>AND</u> gain ≥1.5-<3 months	<input type="radio"/>
	HR >0.70-0.75 <u>AND</u> gain ≥1.5 months	<input type="radio"/>
GRADE 1	HR > 0.75 <u>OR</u> gain <1.5 months	<input type="radio"/>

Mark with ✓ if relevant

Preliminary magnitude of clinical benefit grade (highest grade scored)	4	3	2	1
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Non-curative setting grading - 5 and 4 (substantial benefit), 3 (moderate benefit), 2 and 1 (negligible benefit)

ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

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.

Mark with ✓ if relevant

Adjustments

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

	5	4	3	2	1
Final adjusted magnitude of clinical benefit grade	<input type="checkbox"/>				

Non-curative setting grading - 5 and 4 indicates a substantial magnitude of clinical benefit

OS, overall survival; QoL, quality of life