

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 is ≤ 12 months

GRADE 4	HR ≤ 0.65 <u>AND</u> gain ≥ 3 months	<input type="radio"/>
	Increase in 2 year survival $\geq 10\%$	<input type="radio"/>
GRADE 3	HR ≤ 0.65 <u>AND</u> gain ≥ 2.0 - <3 months	<input type="radio"/>
GRADE 2	HR ≤ 0.65 <u>AND</u> gain ≥ 1.5 - <2.0	<input type="radio"/>
	HR >0.65 - 0.70 <u>AND</u> gain ≥ 1.5 months	<input type="radio"/>
GRADE 1	HR >0.70 <u>OR</u> gain <1.5 months	<input type="radio"/>

Mark with \checkmark 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 indicates a substantial magnitude of clinical benefit

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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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