ESMO-MCBS

ESMO-Magnitude of Clinical Benefit Scale

EVALUATION FORM 2A - ESMO-MCBS v2.0

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 ≥36 months (or not reached with ≥36 months follow-up)

GRADE 4	HR ≤0.70 AND gain ≥12 months	☐
	HR ≤0.65 AND time interim OS gain ≥10% (if the control arm median is not yet reached)	☐
	Increase in 7-year survival ≥10% (if ≥20% of patients on experimental arm have reached 7-year OS)	☐
GRADE 3	HR ≤0.70 AND gain ≥8 - <12 months	☐
	HR ≤0.65 AND time interim OS gain ≥5 - <10% (if the control arm median is not yet reached)	☐
GRADE 2	HR ≤0.70 AND gain ≥6 - <8 months	☐
	HR >0.70 - 0.75 AND gain ≥6 months	☐
	HR ≤0.65 AND time interim OS gain <5% (if the control arm median is not yet reached)	☐
GRADE 1	HR >0.75 OR gain <6 months	☐

Mark with √ if relevant

Preliminary magnitude of clinical benefit score	**4** ☐	**3** ☐	**2** ☐	**1** ☐

ESMO-MCBS, European Society For Medical Oncology-Magnitude of Clinical Benefit Scale; HR, hazard ratio; OS, overall survival.

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ESMO-Magnitude of Clinical Benefit Scale

Quality of life/Grade 3-4 toxicities assessment

Was QoL evaluated as secondary outcome?	☐
Is QoL improved according to the ESMO-MCBS QoL checklist?	☐
Are there fewer 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 using the ESMO-MCBS QoL checklist and/or fewer 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 10-year, also score according to form 1a (treatments with curative potential) and present both scores i.e. A/4

Adjusted magnitude of clinical benefit score	**5** ☐	**4** ☐	**3** ☐	**2** ☐	**1** ☐

Note: Highest magnitude clinical benefit grade that can be achieved in form 2a is grade 5 and the lowest is 1.

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

OS, overall survival; QoL, quality of life.